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The feasibility of combined thermal and nonthermal endovenous ablation in comparison of nonthermal ablation for superficial vein insufficiency from single center

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Abstract

Background: Nonthermal endovenous ablation has been needed high amount of sclerosant for the treatment of saphenous vein insufficiency. However, its safe amount has n

ot been known clearly and nonthermal edovenous ablation should be performed avoidi ng thrombotic complication. This study is to evaluate the feasibility of the combined nonthermal and thermal endovenous ablation technique to reduce the amount of sclero sant in comparison of nonthermal endovenous ablation monotherapy.

Methods: Between June 2018 and May 2020, a total of 327 patients diagnosed with s uperficial vein insufficiency were evaluated retrospectively. 130 patients were includedi n Nonthermal mechanochemical ablation (MOCA, Group I) monotherapy, 197 patient s in combined thermal and nonthermal endovenous ablation treatment (EVLA with M OCA, Group II) from one surgeon of single center. Combined EVLA and MOCA ther apy was mostly performed for patients who had varicose veins in 3 or more veins.

Results: The amount of STD used per number of legs was 5.5±2.05 mL, 4.51±1.2 m L in Group I, Group II respectively ($p<0.001$). The amount of STD used per number of veins was 4.77±1.91 mL, 3.12±1.02 mL in Group I, Group II respectively ($p<0.00$ 1). Recanalization rates were 0% (0/130) within 52 weeks, 2.31% (3/130) after 52 we eks in Group I, 5.58% (11/197) within 52 weeks, 6.60% (13/197) after 52 weeks inG roup II, it was not statistically significant. Complications within 4 weeks Complication rates were 3.84%, 7.11% in Group I, Group II respectively

Conclusions: Combined EVLA and MOCA procedure was effective for those who had 3 or more varicose veins insufficiency. The varicose vein anatomical occlusion at 1 y ear, patient satisfaction and complication rates were included.

Keywords: Chronic venous insufficiency, Thermal endovenous laser ablation, non-the rmal mechanochemical ablation, sclerosant, occlusion

Introduction

Chronic superficial venous insufficiency is very common in modern society. People w ho are affected has been shown a decreased quality of life (QoL). In the past, the ai m of the treatment was on removal of the pathological vein. Since the sclerosant suc h as sodium tetradecyl sulfate (STD) has been introduced, the endovenous ablation be came the major modality for treatment of venous insufficiency in lower leg. In the pa st decades, endovenous laser ablation (EVLA), radiofrequency ablation (RFA), ultrasou

nd-guided foam sclerotherapy (USFS) and mechanochemical ablation (MOCA) have be en gained popularity.

Many trials have been reported these treatment methods are different in the quality of life and the result of surgery. A randomized trial treatment for varicose veins revealed that laser ablation was better than foam sclerotherapy in disease-specific quality of lif e 5 years after treatment [1]. A randomized clinical trial showed that all treatments w ere acceptable in efficiency and a higher failure rate was shown after foam sclerother apy, but postoperative pain and low quality of life were in endovenous laser and strip ping comparing to radiofrequency ablation and foam sclerotherapy [2]. Endovenous th ermal ablations such as laser ablation and radiofrequency ablation have limits related t hermal injury to adjacent tissue which affects the quality of life postoperatively. Nont hermal mechanochemical endovenous ablation with clarivien® avoids thermal injury b ut considerable amount of sclerosant should be infiltrated to close the proximal portio n of the greater saphenous vein (GSV). Even though the adequate amount of sclerosa nt is debated, but considering the side effects of sclerosant, it seems better to use a r educed amount of sclerosant.

The aim of this study was to evaluate that concomitant thermal and nonthermal endo venous ablation is safe and feasible for patients who had 3 or more veins of superfic ial vein insufficiency and also and reduces the amount of sclerosant comparing nonthe rmal MOCA monotherapy.

Methods

Between June 2018 and May 2020, a total of 327 patients diagnosed with superficial vein insufficiency were evaluated retrospectively. Nonthermal mechanochemical ablation (MOCA, Group I) monotherapy was performed on 130 patients, combined thermal an d nonthermal endovenous ablation treatment (EVLA with MOCA, Group II) were perf ormed on 197 patients from one surgeon of single center.

Inclusion criteria were age 18–75 years; symptomatic varicose veins, Clinical Etiologic Anatomic Pathophysiologic (CEAP) class C2–6, GSV incompetence, defined by a refl ux time of more than 0·5 s on duplex imaging (Linear i18LX probe; TUS-AI700, To shiba Medical Systems, Japan) [3]. The patients were examined in the standing positi

on, and reflux was measured after manual compression and release of the calf. Bilateral treatment was permitted, provided that both legs had the same treatment during the same operation. Patients with recurrent varicose veins were also included if the GSV was preserved to the groin on duplex imaging.

A light sedative and analgesic (midazolam) were administered intravenously before the procedure in most patients.

The EVLA procedure was performed under duplex guidance with a 1940 nm GaAIAs laser diode, continuous wave, 600 micrometer fiber (Atoven-1, Diotec, Korea) for all patients. A bare-tip fiber was used for all EVLA treatments. The laser fibere was advanced until 2 cm below the saphenofemoral junction (SFJ), after which the GSV was ablated during withdrawal of the fiber at 10 mm per 7-8 sec with 4-7 watt of laser energy. All treatments were performed in an operation room under tumescent local anesthesia, using a normal saline solution of 0·1 percent lidocaine (N/S 500mL + 2% Lidocaine 25mL). The solution was administered using an infusion pump (Endo-jet, Mesa Medical, Korea) under ultrasound guidance. The aim was to administer 10 ml per cm GSV tumescent anesthesia in the combined Group II.

Clarivein® (Bridgemedica LLC, USA) procedure was performed with two steps of action. Mechanical agitation of the vessel endothelium by a rotating catheter tip. A sclerosant drug sprayed from the tip of the catheter as it is withdrawn to ensure maximal effect. No tumescent anaesthesia was required. All the patients were positioned supine with the leg slightly flexed and abducted to enhance access to both the GSV and the SSV. A Seldinger technique was used to introduce a 5 Fr introducer sheath into either the GSV or SSV under ultrasound guidance and flushed with saline. The ClariVein® OC infusion catheter (Bridgemedica LLC, USA) tip was inserted through the sheath and the tip of the dispersion wire positioned 10 mm distal to the saphenofemoral junction or saphenopopliteal junction. The sheath was withdrawn to just beyond the puncture site to prevent activation of the probe within the sheath. Wire rotation was activated for a few seconds to induce spasm of the proximal vein. With the wire continuing to rotate, infusion of the sclerosant was started simultaneously with catheter pull back. The activated catheter was steadily withdrawn at 1 cm every 7 to 10 s. The sclerosant used was 2.0% liquid sodium tetradecyl sulphate (STD) [4].

Generally, 0.1 ml–0.2 ml of sclerosant is injected every 1 cm pullback on the cathete

r. A completion duplex ultrasound was performed after the procedure to confirm the p atency of the common femoral vein and the deep venous system.

After the procedure, the leg was wrapped in sterile absorbent bandages and covered with a cohesive compression bandage for 48 h. Patients were then instructed to use a compression stocking to the groin for 2 weeks. No specific analgesia was prescribed. All patients were encouraged to resume work and normal activity as soon as they we re able

The study design was approved by the Institutional Review Board of Pusan National University Hospital (PNUH No. 2109-011-107) and was conducted in accordance witht he Declaration of Helsinki.

Follow-up

Patients were asked to document the level of peri and postprocedural pain. A medianf ollow-up period was 1 year. Patients visited on clinic at two weeks, two months, six months, and 1 year and an ultrasound study and clinical exam were performed. Color duplex scan was performed scanning the full length of the treated vein testing for c ompressibility and reflux. A successfully obliterated vein was solid with no visible lu men and could not be compressed, and there was no flow on color duplex and Valsal va.

Statistical analysis

Continuous variables are reported as mean and standard deviation and categorical vari ables as absolute number and percent, unless stated otherwise. Continuous data were c ompared using the Student t test for parametric and non-parametric data, respectively. Categorical data were compared using the Chi-square or Fisher exact tests. Statistical significance was assumed at $p < 0.05$. The statistical analyses were performed using R 3.6.0.

Results

Between June 2018 and May 2020, a total of 327 patients diagnosed with superficial

vein insufficiency were evaluated retrospectively. Nonthermal mechanochemical ablation (MOCA, Group I) monotherapy was performed on 130 patients, combined thermal and nonthermal endovenous ablation treatment (EVLA with MOCA, Group II) were performed on 197 patients from one surgeon of single center.

Clinical characteristics were described in Table 1. Mean age was 51.89±12.95, 54.96±12.53, female was 74.6%, 62.9% in Group I, Group II respectively. According to CEAP Classification, C2-C4 were 99.23%(129/130), 98.47%(194/197) in Group I, Group II respectively.

Table1. Clinical characteristics between MOCA (Group I) and combined EVLA and MOCA (Group II)

Variables	Overall (n=327)	Group I (n=130)	Group II (n=197)	P-value
Age	53.74±12.77	51.89±12.95	54.96±12.53	0.034
Female/Male (%)	221(67.6/106(32.4)	97(74.6)/33(25.4)	124(62.9)/73(37.1)	0.037
CEAP Classification				
C2	163(49.85)	63(48.46)	100(50.76)	
C3	140(42.81)	61(46.92)	79(40.10)	
C4	20(6.12)	5(3.85)	15(7.61)	0.385
C5	2(0.61)	0(0)	2(1.02)	
C6	2(0.61)	1(0.77)	1(0.51)	
Diameter GSV	8.27±2.62	7.72±2.27	8.63±2.77	<0.001
Complication (%)	19(5.81)	5(3.84)	14(7.11)	0.321
Recanalization (%)				
Early (Within 52 weeks)	11(3.36)	0(0)	11(5.58)	0.247
Delayed (After 52 weeks)	16(4.89)	3(2.31)	13(6.60)	
Total (%)	27(8.25)	3(2.31)	24(12.18)	0.003

Number of legs (%)				
1	88(26.91)	70(53.85)	18(9.14)	<0.001
2	239(73.09)	60(46.15)	179(90.86)	
Number of veins (%)				
1	68(20.79)	55(42.3)	13(6.6)	<0.001
2	103(31.50)	55(42.3)	48(24.37)	
3	98(29.97)	14(10.78)	84(42.64)	
4	58(17.74)	6(4.62)	52(26.39)	
Total STD (mL)	8.14±2.64	7.56±2.71	8.52±2.54	<0.001
STD/Leg (mL)	4.91±1.69	5.5±2.05	4.51±1.27	<0.001
STD/Vein (mL)	3.77±1.65	4.77±1.91	3.12±1.02	<0.001

CEAP Clinical Etiologic Anatomic Pathophysiologic (CEAP), STD Sodium tetradecyl sulphate
MOCA mechenochemical ablation, EVLA endovenous laser ablation

Diameter GSV was 72±2.27cm, 8.63±2.77cm in Group I, Group II respectively, it was statistically significant (p<0.001). Patients with varicose veins in both legs were 46.1 5%(60/130), 90.86%(179/197) in Group I, Group II respectively (p<0.001).

Patients with 3 or more varicose veins were 15.40%(20/130), 69.03%(136/197) in Gro up I, Group II respectively (p<0.001).

Totally used sclerosant such as sodium tetradecyl sulfate (STD) was 7.56±2.71 mL,

8.52±2.54 mL in Group I, Group II respectively (p<0.001). The amount of STD used per number of legs was 5.5±2.05 mL, 4.51±1.2 mL in Group I, Group II respectively (p<0.001). The amount of STD used per number of veins was 4.77±1.91 mL, 3.12±1. 02 mL in Group I, Group II respectively (p<0.001).

Complication rates were 3.84%, 7.11% in Group I, Group II respectively (Table 2). R ecanalization was 0% (0/130) within 52 weeks, 2.31% (3/130) after 52 weeks in Gro up I, 5.58% (11/197) within 52 weeks, 6.60% (13/197) after 52 weeks in Group II, it was not statistically significant (Table 3).

Table 2. Type of complications between MOCA (Group I) and combined EVLA and MOCA (Group II)

Type of Complication	Group I (n=130)	Group II (n=197)
	within 4 weeks	within 4 weeks
edema	0	2
hemoglobinuria	1	0
local skin infection	0	1
pain along vein	0	1
pigmentation	2	1
pigmentation thrombophebitis	0	0
rash, thrombophlebitis	2	8
wound oozing	0	1
Total (%)	5(3.85)	14(7.11)

MOCA mechenochemical ablation, EVLA endovenous laser ablation;

Table 3. Type of recanalization between MOCA (Group I) and combined EVLA and MOCA (Group II)

Type of of recanalization	Group I (n=130)		Group II (n=197)	
	Early	Delayed	Early	Delayed
both gsv prox	0	0	3	1
both gsv thigh	0	0	1	0
both ssv prox	0	1	0	0
lt gsv bk	0	0	0	1
lt gsv thigh	0	0	0	3
lt gsv thigh, lt ssv	0	0	0	1
lt sfj	0	1	0	0
lt ssv	0	0	2	2
lt ssv, gsv bk	0	0	1	0
rt gsv bk, lt gsv thigh	0	0	0	1
rt gsv thigh	0	0	3	1
rt gsv, lt ssv	0	1	0	0
rt ssv	0	0	1	3

Total (%)	0(0)	3(2.31)	11(5.58)	13(6.60)

MOCA mechenochemical ablation, EVLA endovenous laser ablation
gsv great saphenous vein, ssv small saphenous vein, sfj saphenofemoral junction, bk below knee

Discussion

In this study, combined EVLA and MOCA therapy was mostly performed for patients who developed varicose veins in 3 or more veins. After 1year follow-up after surgery, the insufficient varicose vein occlusion rate is high, and the amount of STD used wa s also reduced per number of legs and per number of veins. Bilateral procedures can be successfully performed, and these are well tolerated as can multiple veins in the b oth leg. MOCA monotherapy was also excellent in the patient's quality of life and va ricose vein occlusion rate with the usual amount of STD used. ClariVein can be used to ablate long and short saphenous varicose veins on a walk-in–walk-out basis.

The volume of sclerosant used was not predetermined but adjusted on a case-by-case basis by continuous duplex monitoring of the mechanical and chemical effect to ensue spasm and collapse of the vein, while not exceeding the safe dose of sclerosant. Gen erally, 0.1 ml–0.2 ml of sclerosant is injected every 1 cm pullback on the catheter. V ein diameter was determined by duplex ultrasound measurement from the widest part of the treated vein in the supine position excluding the first 2 cm of vein and any lo calized venous blowouts.

When adhering to safe dosage levels, sclerosants with higher concentrations potentially limit the extent of treatment. By Lam, at 6 weeks post-treatment duplex ultrasound sh owed that 100%, 96.4% and 56.5% were occluded using 2% Polidocanol liquid, 3% Polidocanol liquid and 1% Polidocanol microfoam in the mechano-chemical ablation r espectively [5].

The frequency of recanalization after 2 years from the VenaBlock procedure was signi ficantly higher than after laser treatment (37.2 vs. 8.7%) [6].

At eight weeks' follow-up, there was only partial obliteration in 13/393 (3.3%) veins after mechanochemical endovenous ablation with ClariVein® [7].

Recently, a randomized controlled crial of endovenous laser ablation versus mechanoch emical ablation with ClariVein was reported. Both EVLA and MOCA were highly effi cacious in treating superficial vein insufficiency. Both resulted in low procedural pain

with a short recovery time. Axial occlusion rates were higher after EVLA [8-10]. The outcomes were intra-procedural ablation pain scores and anatomical occlusion at 1 yea r. Post-procedural pain, venous clinical severity score, quality of life, patient satisfacti on and complication rates were included.

In our study, both combined EVLA and MOCA (Group II), MOCA monotherapy (Gro up I) were highly efficacious in treating superficial venous insufficiency. Patients impr oved significantly in terms of disease severity, symptoms, low procedural pain with as hort recovery time. About recanalization, of 24 patients (Group II) who had recanaliza tion, 16 patients who used 4 watt of laser energy, 7 patients who used 5 watt of las er energy, and 1 patient who used 6 watt of laser energy during EVLA. Recanalizatio n rate was low in the case of combined procedure using 7 watt of laser energy. Lase r energy with 7watt has been mainly used since May 2018.

Tumescent anesthesia is currently required for endothermal ablation technique and carr ies the risk of thermal-related complications such as neuralgia, skin burn and prolonge d pain [11,12]. The insertion of tumescence itself can also be painful and cause comp lications. The ClariVein occlusion catheter is a relatively minimally invasive approach with a liquid sclerosant infusion. It has the advantage of eliminating the need for tum escent anesthesia and the risks of heat related injury to the surrounding tissue and str uctures. It has been shown to be safe and efficacious in its initial trials [13,14] not o nly for the great saphenous vein but also for the short saphenous vein [15,16]. Proce dure times and intra/post-procedural pain scores have better than for RFA and EVLA [17,18]. Kwon et al recommended that caution should be exercised when the epifascia l GSV tributary is treated during the ClariVein procedure because of its hyperpigment ation as a complication [19].

Conclusion

The occlusion rate of GSV with EVLA and MOCA combination therapy was effective, and the total amount of STD per number of lesion veins and legs could be reduced, thereby reducing side effects.

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All authors have read and agreed to the published version of the manuscript.

Institutional Review Board Statement: The study was conducted according to the gu idelines of the Declaration of Helsinki. The study design was approved by the Institut ional Review Board of Pusan National University Hospital (PNUH No. 2109-011-107).

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