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Original Article

Effectiveness of Endovenous Radiofrequency Ablation for Elderly Patients with Varicose Veins of Lower Extremities

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Objective: The purpose of this study was to evaluate safety and effectiveness of endovenous radiofrequency ablation (RFA) for elderly patients.

Materials and Methods: We enrolled 140 patients (194 limbs) who underwent RFA for varicose veins of lower extremities. Patients were divided into two groups; elderly patients (more than 75 years old, E-group, n=36) and young patients (under 75 years old, Y-group, n=104), and perioperative data were analyzed and compared between two groups.

Results: In E-group, there were more than patients with hypertension, ischemic heart disease, malignant tumor, and cerebrovascular disease. A partial recanalization was observed in only one limb (0.6%) in Y-group. Endovenous heat induced thrombosis (EHIT) was identified four limbs (2.8%) in Y-group and two limbs (4.1%) in E-group. All EHITs were class 1 by Kabnick classification, and they disappeared within one month after interventions, without antithrombotic therapy. No other major complications were observed. There were no significantly differences for preoperative mean venous clinical severity scores (VCSS) (Y:E=4.84:4.47) and postoperative VCSS (Y:E=1.16:1.19, 0.35:0.58, 0.15:0.06, 0.05:0.06 at 1, 3, 6, 12 months after) in both groups.

Conclusion: RFA for elderly patients is a safe and effective strategy for varicose veins of lower extremities.

Keywords: varicose vein, radiofrequency ablation, elderly patient, venous clinical severity score

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Introduction

Varicose veins (VVs) of lower extremities are common vascular diseases. In Japan, there are more than thirty thousand patients who are treated for VVs per year.[1,2] In these cases, patients over 70 years old were about 30%, and have increased every year.[1]

Previously, the treatment of VVs has been surgery involving high ligation and stripping of the saphenous veins.[3] However, endovenous techniques, such as endovenous laser ablation (EVLA) and endovenous radiofrequency ablation (RFA), have recently been introduced.[2] In particular, RFA is a relatively new treatment and is a minimally invasive intervention that has become one of common alternatives in Japan.

Though RFA is associated with fewer postoperative complications,[4] there are few evidences for RFA of advanced age patients. The aim of this study was to investigate mid-term result of RFA for VVs in elderly patients.

Materials and Methods

This retrospective study was approved by the institutional review board, and a written informed consent was obtained from all of the patients.

A total of 173 patients underwent surgical interventions for VVs in our institution between May 2015 and October 2017. We defined VVs as varicose veins caused by saphenous reflux. All patients had visited outpatient clinics for twelve months. In these cases, patients with preoperative vein diameter at sapheno–femoral junction of less than 10 mm were selected for RFA. When the diameter was more than 10 mm, stripping of saphenous vein was undertaken. The patients treated with stripping were excluded in this study. Therefore, 194 limbs in 140 patients were enrolled in our study.

The 140 enrolled patients were divided into two groups; elderly patients (more than 75 years old, E-group, n = 36, leg = 49) and young patients (under 75 years old, Y-group, n = 104, leg = 145), and perioperative data were analyzed and compared between two groups. The reason we chose

elderly as 75 years and older is because this is the definition of elderly in Japan's health care system.

In our institution, all patients with varicose veins of the lower extremities underwent both ultrasonography and magnetic resonance venography (MRV) to detect deep vein thrombosis (DVT). Because MRV could detect DVT in middle femoral veins that might be difficult to detect using ultrasonography,[5] we performed MRV as a routine examination.

RFA was performed using Closure Fast™ catheters (Covidien, Mansfield, MA, USA). As RFA procedure, the patient's leg was prepped with disinfectant solution and draped in a sterile fashion. With ultrasound guidance, the vein was cannulated. The RFA catheter was accessed with a 7 Fr sheath, and RFA catheter was sent through it to the sapheno–femoral junction. The radiofrequency energy was delivered to 120°C. A venous segment 7 cm in length was treated in 20-s cycles. In all cases, the anesthesia methods were performed with femoral nerve block and tumescent local anesthesia.

To assess endovenous heat induced thrombosis (EHIT) and the occlusion rate of the treated veins, duplex ultrasound scannings were performed at 1 day, 1 week, 1 month, 3 months, 6 months, and 1 year.

The following characteristics were analyzed at the time of diagnosis: demographic features, predisposing family history and past personal history, clinical features, treatment, and outcome. Preoperative examinations included echocardiographic studies, radiologic images, and results of routine laboratory tests (including hematological value, lipid parameter, liver and renal function, and inflammatory parameters).

There were preoperative patients' characteristics in **Table 1**. Ninety-two patients (65.7%) were female. The mean age was 68.3 ± 9.5 years (35–85 years). A total of 107 patients (78.8%) and 155 limbs (79.9%) had VVs of the great saphenous veins, and 33 patients (21.2%) and 39 limbs (20.1%) had short saphenous veins. VVs were evaluated according to the Clinical Etiology Anatomy Pathophysiology (CEAP) classification before RFA: 123 limbs (87.9%) were graded as C2 and C3.

Diabetes mellitus (DM) was defined as the recent use

Table 1 Demographic preoperative characteristics of all patients

	Y-group (n=104)	E-group (n=36)	p value
Age (year)	64.6±8.5 (35–74)	78.9±2.7 (75–85)	<0.001
Sex (female)	69 (66.3%)	23 (63.9%)	0.791
Prevalence			
Hypertension	28 (26.9%)	23 (63.9%)	<0.001
Dyslipidemia	58 (55.8%)	22 (61.1%)	0.580
DM	17 (16.3%)	9 (25.0%)	0.253
CKD	0 (0.0%)	0 (0.0%)	
COPD	9 (8.7%)	7 (19.4%)	0.081
Ischemic heart disease	2 (1.9%)	11 (30.6%)	<0.001
Malignant tumor	7 (6.7%)	7 (19.4%)	0.029
Cerebrovascular disease	0 (0.0%)	3 (8.3%)	0.003
Bone disorder	8 (7.7%)	6 (16.7%)	0.124
Digestive disease	10 (9.6%)	1 (2.8%)	0.191
Blood disorder	3 (2.9%)	0 (0.0%)	0.306
Genital organ disease	12 (11.5%)	2 (5.6%)	0.282
Thyroid disorder	4 (3.8%)	3 (8.3%)	0.290
Ejection fraction (%)	69.1±4.7	69.7±6.2	0.547
Length of varicose veins (year)	12.1±12.4 (1–49)	12.1±13.6 (1–48)	0.974
Varix of GSV	80 (76.9%)	27 (75.0%)	0.816
(number of limbs)	(119, 82.1%)	(36, 73.5%)	0.167
Varix of SSV	24 (23.1%)	9 (25.0%)	0.816
(number of limbs)	(26, 17.9%)	(13, 26.5%)	0.158
CEAP classification			
C2	54 (51.9%)	16 (44.4%)	0.433
C3	37 (35.6%)	16 (44.4%)	0.348
C4a	10 (9.6%)	3 (8.3%)	0.821
C4b	3 (2.9%)	1 (2.8%)	0.974

DM: diabetes mellitus; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; GSV: great saphenous vein; SSV: small saphenous vein; CEAP: clinical etiology anatomy pathophysiology

of anti-diabetic drugs, fasting blood glucose >126 mg/dl, and/or hemoglobin A_{1c} >6.5%. Chronic kidney disease (CKD) was defined as estimated glomerular filtration rate (eGFR) <30 ml/min/1.73 m^2.

Continuous variables are expressed as medians±SD with ranges when appropriate. Categorical variables are expressed as numbers (%) and were compared using the Student's t-test for continuous variables. Examinations of parametric data were used with contingency tables, with Fisher's exact test, as appropriate. Differences were considered significant at $p<0.05$. Stat View for Windows version 6.0 (SAS Institute Inc., Cary, NC, USA) software program was used for all calculations.

Results

In E-group, there were more patients with hypertension (Y:E=26.9:63.9%, $p<0.001$), ischemic heart disease (Y:E=1.9:30.6%, $p<0.001$), malignant tumor (Y:E=6.7:19.4%, $p=0.029$), and cerebrovascular disease (Y:E=0.0:8.3%, $p=0.003$), compared with Y-group (**Table 1**). There was no significant difference in the length of VVs between both groups. There were also no significant differences in CEAP classifications between both groups.

Major complications after RFA are shown in **Table 2**. In one limb (0.6%), a partial recanalization was observed in Y-group. Therefore, the occlusion rate of the treated veins was 99.4%. The cause of recurrent varicose vein was residual tributary.

EHITs were identified two limbs (4.1%) in E-group and four limbs (2.8%) in Y-group (**Table 2**, $p=0.665$). All EHITs were class 1 by Kabnick classification,[6] and they naturally disappeared within one month after interventions, without antithrombotic therapy. There was no other major complication such as DVT and nerve injury in any of the patients.

There were minor complications after RFA in **Table 3**. There were more patients with edema in E-group than Y-group (Y:E=1.0:13.9%, $p<0.001$). Other minor complications, such as pain, numbness, induration, muscle clamping, localized hot flashes, dullness, and red flare, were equally observed after RFA in both groups. As a result, procedure pain (Y:E=19.2:27.8%, $p=0.285$) and procedure bruising (Y:E=19.2:11.1%, $p=0.268$) were evenly noted in both groups.

There were no significant differences for preoperative mean venous clinical severity scores (VCSS) (Y:E=4.84:4.47) and postoperative VCSS (Y:E=1.16:1.19, 0.35:0.58, 0.15:0.06, 0.05:0.06 at 1, 3, 6, 12 months after) in both groups (**Table 4**). Between both groups, each postoperative VCSSs improved from preoperative VCSS (data not shown, $p<0.0001$).

Table 2 Postoperative major complication after endovenous radiofrequency ablation

	Y-group (leg=145)	E-group (leg=49)	p value
EHIT	4 (2.8%)	2 (4.1%)	0.665
Recanalization of vein	1 (0.6%)	0 (0.0%)	0.558

EHIT: endovenous heat induced thrombosis

Table 3 Postoperative minor complication after endovenous radiofrequency ablation

	Y-group (n=104)	E-group (n=36)	p value
Pain	24 (23.1%)	11 (30.6%)	0.173
Numbness	15 (14.4%)	1 (2.8%)	0.135
Induration	8 (7.7%)	0 (0.0%)	0.143
Muscle cramping	5 (4.8%)	4 (11.1%)	0.421
Localized hot flashes	3 (2.9%)	1 (2.8%)	0.974
Dullness	2 (1.9%)	1 (2.8%)	0.674
Red flare	1 (1.0%)	0 (0.0%)	0.558
Edema	1 (1.0%)	5 (13.9%)	<0.001
Procedure pain	20 (19.2%)	10 (27.8%)	0.285
Procedure bruising	20 (19.2%)	4 (11.1%)	0.268

Table 4 Perioperative changes in venous clinical severity score

	Y-group (n=104)	E-group (n=36)	p value
Pre-operation	4.84±1.12	4.47±0.85	0.076
After 1 month	1.16±1.29	1.19±1.31	0.901
After 3 months	0.35±0.81	0.58±0.94	0.148
After 6 months	0.15±0.59	0.06±0.33	0.343
After 12 months	0.05±0.29	0.06±0.33	0.899

Discussion

Compared with conventional surgery like stripping of the saphenous veins, the effectiveness and safety of endovascular treatment of VVs have been well demonstrated in a number of studies. Endovenous techniques have been recommended for the treatment of VVs by the Society for Vascular Surgery and the American Venous Forum.[7] These methods have several advantages, including decreased pain, less morbidity, shorter hospital stay, and faster return to work. More recently, Rasmussen et al. reported that RFA yielded results that were at least similar to those of EVLA.[8] Specifically, RFA was reported to be associated with significantly less post-procedural pain than EVLA. Though RFA is associated with fewer postoperative complications,[4] there is little evidence for RFA of advanced age patients. We presented that there were low

postoperative complications in both young and elderly patients in **Table 2**. The results of our study shows that RFA for elderly patients is as safe and effective as for younger patients. After RFA, VCSSs of both groups decreased sufficiently in the present study.

In our study, there were more patients with ischemic heart disease and/or cerebrovascular disease in E-group (**Table 2**). Aging is an important factor of the causes for arteriosclerosis,[9] and is the reason for more patients having malignant tumor in E-group (**Table 1**). Though there was no significant difference in preoperative ejection fraction between groups, more patients with postoperative edema were in E-group than in Y-group. The reason for this is that valvular heart disease is more prevalent in elderly patients. However, there was no significant difference in patients with other minor postoperative complications between both groups, and so we showed that RFA was an adequate intervention for advanced age patients.

In this present study, only one limb of Y-group showed evidence of partial recanalization on follow-up (**Table 2**). This procedure demonstrated successful vein occlusion in 99.4% limbs. Encouraging occlusion rates of saphenous veins after RFA have been reported in several studies. Kapoor et al. presented patients with saphenous venous insufficiency seen 100% closure on doppler studies along with lesser complications.[10] Nordon et al. reported that vein occlusion was 97% for RFA after three months.[11] Proebstle et al. achieved an initial vein occlusion rate of 100% and 91.9% at 5 years.[12] Although dilation of vein diameter[13] and obesity[14] were factors that affected postoperative recanalization, few authors suggested an association between aging and recanalization or recurrence. In our study, there was no recanalization in E-group, and so aging does not seem to be a factor of recanalization after RFA.

The rate of EHIT was reported to have a much lower incidence in RFA (2.7%–3.4%).[4,15] According to previous studies, risk factors for EHIT include age. However, Sufian et al. reported that there was no relationship between EHIT and age by adopting EVLA,[16] and so it remains controversial whether age is a risk factor for EHIT. Additionally, few studies have reported a relationship between EHIT and age by performing RFA. We demonstrated that there were two limbs (4.1%) in E-group and four limbs (2.8%) in Y-group, and that there was no significant difference between both groups in incidence rate of EHIT (**Table 2**, $p = 0.665$). Aging may be not a risk factor of EHIT.

There was comparison of patients who underwent RFA with patients who underwent stripping of the saphenous veins in our study. However, elderly patients were only three, so we could not compare RFA and stripping adequately. However, there are many studies[17] that have demonstrated RFA is superior to stripping. Additionally, Sutzko et al.[18] presented that there was no significant difference in the improvement in CEAP and VCSS between patients younger and older than 65 years. Therefore, it may be concluded that RFA can be performed safely in the elderly compared to conventional treatment.

The results of this study had certain limitations. The present study is a retrospective study, and so the result was limited by the relatively small number of patients included because our study was a single-center experience. Despite these limitations, our study was able to show that RFA was a clinically useful procedure for elderly patients.

Conclusion

For elderly patients, RFA is a safe and effective strategy for varicose veins treatment of lower extremities. It might be considered clinically useful for a wide-range ages.

Disclosure Statement

There is no conflict of interest for this article.

Author Contributions

Study conception: KT, TM
Data collection: KT, SS
Analysis: KT
Investigation: KT
Writing: KT
Funding acquisition: none
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

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