Chronic Venous Disease Treated with Endovenous Microwave Ablation: Long-Terms Results and Quality of Life

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Background: *Microwave ablation is considered to be safe for treatment in chronic venous disease patients, but data is lacking about its long-terms results. The present study aimed to evaluate the effectiveness of endovenous microwave ablation.*
Material and Method: *From January 2009-June 2012, 100 patients underwent endovenous microwave ablation. Demographic data, post-operative complication, and CIVIQ-2 questionnaire scores were recorded. Microwave energy was set at 50-65 watts and the pull back speed was 3 cm/minute.*
Results: *C2 was a common finding, (59.6%). Mean follow-up time was 25.2 months and the most immediate complication was numbness (32.1%) with permanent numbness at 3.8%. Quality of life as determined by CIVIQ-2 score changed from 32 before operation to 24 after operation ($p<0.001$). Complete venous occlusion rate was 79.8% and the rate of partial venous occlusion with no venous reflux was 8.7%.*
Conclusion: *Endovenous microwave ablation can be used safely. It could be an alternative treatment for patients with chronic venous disease.*

Keywords: *CEAP, Ablation, Microwave, CIVIQ-2, Venous insufficiency, Varicose veins*

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Venous insufficiency of the great saphenous vein (GSV) and small saphenous vein (SSV) is the most common cause of varicose veins in the lower extremities, affecting about 25% of the population. Symptoms vary widely from mild discomfort and swelling to non-healing venous stasis ulcer formation. The Clinical Etiological Anatomic and Pathologic (CEAP) classification system, first published in 1994 and revised in 2004, is widely accepted by clinicians and researchers for characterizing the varying severity of vein disease[1]. Surgical treatment of varicose veins includes high ligation and saphenous vein stripping with or without phlebectomy, and up until the past few years this procedure was the one of the most commonly used by surgeons worldwide[2,3]. With the introduction of less invasive techniques, treatment preference has shifted to endovenous ablation of the GSV or SSV. Several forms of endovenous treatment such as endovenous laser ablation (EVLA), radiofrequency ablation (RFA), and foam sclerotherapy (FS) have been described in the literature and are commercially available. A recent meta-analysis suggested that RFA and EVLA are superior in achieving anatomical success compared with surgery, and that they help to achieve a reduction of pain and an earlier return to daily activities[4,5]. The other source of energy, microwaves, has lately come to be considered to be safe and to obtain good clinical outcomes in treating these groups of patients[6]; however, more long-term follow-up and more cases of patients with microwave treatment are needed to demonstrate the true benefits of this technique. The present study aimed to evaluate the effectiveness of endovenous microwave ablation (EVMA) for chronic venous disease patients.

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Material and Method

The present study protocol was approved by the Rajavithi Hospital Ethics Committee, and informed consent was obtained from participants. From January 2009 to June 2012, all patients who underwent endovenous microwave ablation were included in this

study. Patients who failed to attain follow-up or refused to participate in the present study were excluded. The patients' age, sex, CEAP classification, pre- and postoperative color Doppler ultrasound, intraoperative findings, post-operative complications, and CIVIQ-2 questionnaire score for assessment of pre-operative and postoperative quality of life were recorded. Depending on the patient's venous status, either the ultrasound-guided venous cut down technique or the ultrasound- guided Seldinger technique was used to canulate the microwave probe into the vein. After canulation into the vein, the tip of the microwave probe was placed 2 cm from the saphenofemoral junction (SFJ), or 2 cm from the saphenopopliteal junction in the case of small saphenous vein reflux. The microwave power (MICROTAZE OT-110M, JAPAN) was set at 50-65 watts depending on vein diameter, and the pull back speed of the microwave catheter was 3 cm/minute along the vein. For those cases of perforator reflux, the authors carried out the normal procedure for GSV ablation but focused more on the location of GSV and the perforator vein, extending the ablation time to 30 seconds at this point. After ablation was completed, the entire vein was evaluated by duplex ultrasound. The procedure was performed in the operation room with tumescent local anesthesia and intravenous anesthesia. The tumescent technique could help to prevent thermal injury to the skin and also to compress the vein during microwave ablation to achieve successful venous occlusion. Venous occlusion was defined as present when no evidence of blood flow was observed. Partially occluded veins were defined as having less than or equal to 5 cm segment of flow within the SFJ or an otherwise occluded vein trunk. Nonoccluded veins were defined as having greater than 5 cm of flow in any treated vein segment[7]. All patients were advised to wear a compression stocking for 14 days. They were discharged home on the day of the operation and early ambulation was encouraged. No thromboembolic prophylaxis drug was introduced in this study. Patients were asked to come back at intervals of one week, six months, one year and then annually for outpatient review.

Statistical analysis

Data were presented as mean $\pm$ standard deviation (SD) or median (range) for continuous variables and number (%) for categorical variables. Wilcoxon's signed-rank test was used for analyzing pre-operative and postoperative quality of life score. A p-value <0.05 was considered statistically significant. Sample size calculation was based on a venous occlusion rate of 94% after microwave ablation[8] with 95%CI of 94$\pm$5%. Therefore, 87 subjects were needed. Almost 10% dropout rate was calculated, 95 patients were required.

Results

One hundred patients underwent a total of 104 procedures. The most common presentation was pain (77.6%) and CEAP classification C2 was common, at 59.6%. The GSV was more commonly involved than the SSV and the perforator vein. All demographic data is shown in Table 1. The mean follow-up time was 25.2 months and the most immediate complication was numbness (32.1%) with permanent numbness at 3.8%. Quality of life assessed by CIVIQ-2 score changed from 32 pre-operatively to 24 postoperatively (p<0.001) (Table 2).

Postoperative Doppler ultrasound found that the complete venous occlusion rate was 79.8% and the rate of partial venous occlusion with no venous reflux was 8.7% after follow-up. No deep vein thrombosis or other serious complications were found in the present study.

Discussion

The traditional and still most common approach for treating SFJ incompetence and GSV reflux is saphenofemoral disconnection and GSV stripping to the knee. Traditional surgical therapies have also been used to treat symptomatic SSV. When encountered, incompetent perforator veins were ligated in an open (Linton) or endoscopic fashion (subfascial endoscopic perforator surgery). Despite being considered a minor surgical procedure, complications are not uncommon and include recurrence (19-35%), nerve injury (4-25%), hematoma (<30%), wound infection (2-15%), deep vein thrombosis (<2%) and pulmonary embolism (0.2-0.5%)[9]. However, endovenous ablation procedures have more recently been reported to be safe and effective methods of eliminating the proximal portion of the GSV, SSV and even tributary and perforator veins from the venous circulation with faster recovery and better cosmetic results than stripping[10-12]. The three currently available methods of achieving ablation of diseased veins are: the closure procedure, using a radiofrequency (RF) catheter; the endovenous laser ablation procedure and endovenous chemical ablation with ultrasound-guided foam sclerotherapy. A meta-analysis of all therapies for saphenous insufficiency was performed by van den Bos et al[5]. The pooled

Table 1. Demographic data of 100 chronic venous disease patients with 104 procedures

	Number (%) or Mean ± SD
Age (year)	52.5±10.2
Male: Female	30: 70
Vein diameter (mm)	9.5±1.1
Reflux time (mm)	2,427±1,086
CEAP classification	
C1	2,427±1,086
C2	62 (59.6)
C3	18 (17.3)
C4	11 (10.6)
C5	8 (7.7)
C6	2 (1.9)
Anatomy	
Great saphenous vein	82 (78.9)
Small saphenous vein	12 (11.5)
Perforator vein	3 (2.9)
Great saphenous & small saphenous vein	7 (6.7)

Table 2. Post endovenous microwave ablation outcomes and quality of life

Outcomes	Number (%) or median (min, max)
Venous occlusion	
Complete	83 (79.8)
Partial with no reflux	9 (8.7)
Partial with reflux	3 (2.9)
No	9 (8.6)
Complication	
Ecchymosis	23 (22.1)
Thrombophlebitis	4 (3.8)
Skin burn	6 (5.8)
Dyschromia	13 (12.5)
Numbness	4 (3.8)
CIVIQ2 score	
Pre-operation	32 (20, 76)
Postoperation at 1 year	24 (18, 71)

analysis included 12,320 limbs with an average follow-up period of 32 months. Stripping was associated with a 78% (range, 70-94%) reflux-free rate, and foam sclerotherapy had a reflux-free rate of 77% (range, 69-84%) at three years. The older RF catheter had an 84% closure rate (range, 75-90%) after three years, and the laser ablation (all energy levels and all wavelengths) yielded a 94% (range, 87-98%) closure rate at three years.

In general, all treatments for varicose veins were well tolerated, without significant periprocedural adverse effects; in particular, deep vein thrombosis and pulmonary embolism in these studies were very infrequently reported. In radiofrequency ablation, other complications such as saphenous nerve paresthesia (13%), superficial phlebitis (0-20%), hematoma (7%), thermal skin injury (7%), paresthesia (<1%) and leg edema (<1%) have been reported[13].

In 2009, Subwongcharoen et al[6]. found that EVMA appeared to be another extremely safe and effective technique to treat varicose veins and that the best ablation effect could be obtained using a

microwave generator with a 50-W power setting; however, the study did not investigate long-term follow-up or quality of life evaluation. A retrospective study by Mao J et al[8] comparing endovenous laser ablation and microwave ablation for great saphenous varicose veins, demonstrated that venous occlusion rates of EVLA and EVMA at six months postoperation were 90.1% and 94.8% respectively. The most common complications were ecchymosis, skin burn and numbness with rates of 17.4%, 9.9%, and 10.7%, respectively. Even though the present study increased microwave power to 50-65 watts for ablation, a lower occlusion rate of 79.8% was demonstrated. One reason for the difference in occlusion rate in this study could be that the mean follow-up time was longer (25.2 months) than the previous study[8]; furthermore, the diameter of the vein that had strong impact on the occlusion rate was not mentioned in the study by Mao J et al. When we compare our results with RF ablation from other studies, our reflux-free rate was 88.5% which is lower than that of RF ablation. More paresthesia and ecchymosis were found (3.8% and 22.1% respectively) in this study. Gale et al[14] reported that all patients enjoyed improved quality of life according to the Chronic Venous disease Questionnaire (CVIQ-2) at 1 year after RF ablation, and this was similar to the findings of our study using microwave ablation.

Conclusion

Endovenous microwave ablation can be used safely and effectively for both GSV and SSV reflux; however the reflux-free rate in the present study was less than that obtained by traditional endovenous RF or endovenous laser ablation. It could be an alternative treatment for chronic venous disease patients.

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Potential conflicts of interest

None.

References

1. Beebe HG, Bergan JJ, Bergqvist D, Eklof B, Eriksson I, Goldman MP, et al. Classification and grading of chronic venous disease in the lower limbs. A consensus statement. Eur J Vasc Endovasc Surg 1996; 12: 487-91.
2. Lees TA, Beard JD, Ridler BM, Szymanska T. A survey of the current management of varicose veins by members of the Vascular Surgical Society. Ann R Coll Surg Engl 1999; 81: 407-17.
3. Perrin M, Guidicelli H, Rastel D. Surgical techniques used for the treatment of varicose veins: survey of practice in France. J Mal Vasc 2003; 28: 277-86.
4. Rautio T, Ohinmaa A, Perala J, Ohtonen P, Heikkinen T, Wiik H, et al. Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. J Vasc Surg 2002; 35: 958-65.
5. van den Bos R, Arends L, Kockaert M, Neumann M, Nijsten T. Endovenous therapies of lower extremity varicosities: a meta-analysis. J Vasc Surg 2009; 49: 230-9.
6. Subwongcharoen S, Praditphol N, Chitwiset S. Endovenous microwave ablation of varicose veins: in vitro, live swine model, and clinical study. Surg Laparosc Endosc Percutan Tech 2009; 19: 170-4.
7. Nicolini P. Treatment of primary varicose veins by endovenous obliteration with the VNUS closure system: results of a prospective multicentre study. Eur J Vasc Endovasc Surg 2005; 29: 433-9.
8. Mao J, Zhang C, Wang Z, Gan S, Li K. A retrospective study comparing endovenous laser ablation and microwave ablation for great saphenous varicose veins. Eur Rev Med Pharmacol Sci 2012; 16: 873-7.
9. Beale RJ, Gough MJ. Treatment options for primary varicose veins-a review. Eur J Vasc Endovasc Surg 2005; 30: 83-95.
10. Fischer R, Linde N, Duff C, Jeanneret C, Chandler JG, Seeber P. Late recurrent saphenofemoral junction reflux after ligation and stripping of the greater saphenous vein. J Vasc Surg 2001; 34: 236-40.
11. Frullini A, Cavezzi A. Sclerosing foam in the treatment of varicose veins and telangiectases: history and analysis of safety and complications. Dermatol Surg 2002; 28: 11-5.
12. Proebstle TM, Gul D, Lehr HA, Kargl A, Knop J. Infrequent early recanalization of greater saphenous vein after endovenous laser treatment. J Vasc Surg 2003; 38: 511-6.
13. Murad MH, Coto-Yglesias F, Zumaeta-Garcia M, Elamin MB, Duggirala MK, Erwin PJ, et al. A systematic review and meta-analysis of the treatments of varicose veins. J Vasc Surg 2011; 53 (5 Suppl): 49S-65S.

14. Gale SS, Lee JN, Walsh ME, Wojnarowski DL, Comerota AJ. A randomized, controlled trial of endovenous thermal ablation using the 810-nm wavelength laser and the Closure PLUS radio frequency ablation methods for superficial venous insufficiency of the great saphenous vein. J Vasc Surg 2010; 52: 645-50.

โรคเส้นเลือดดำบกพร่องเรื้อรังรักษาด้วยวิธีใช้คลื่นไมโครเวฟผ่านเข้าในเส้นเลือด: ศึกษาผลระยะยาวและคุณภาพชีวิต

สมบูรณ์ ทรัพย์วงศ์เจริญ, เศกสันต์ ชัยวิเศษ

ภูมิหลัง: *การใช้คลื่นวิทยุไมโครเวฟทำลายเส้นเลือดดำถือว่าเป็นวิธีที่ปลอดภัยในการรักษาภาวะเส้นเลือดดำบกพร่องเรื้อรังที่ขา แต่ยังไม่มีข้อมูลถึงผลการรักษาในระยะยาว การศึกษานี้มีวัตถุประสงค์เพื่อประเมินประสิทธิผลของการรักษาด้วยวิธีการนี้*

วัสดุและวิธีการ: *การศึกษาเริ่มต้น เดือนมกราคม พ.ศ. 2552 ถึง เดือนมิถุนายน พ.ศ. 2555 คนไข้ 100 ราย ที่เป็นเส้นเลือดดำบกพร่องเรื้อรังได้รับการรักษาด้วยวิธีใช้คลื่นไมโครเวฟ เก็บข้อมูลพื้นฐาน, ภาวะแทรกซ้อน และคุณภาพชีวิต ระดับพลังงานคลื่นไมโครเวฟได้ตั้งไว้ที่ 50-56 วัตต์ ความเร็วของการถอยสายที่ส่งคลื่นไมโครเวฟ 3 เซนติเมตรต่อนาที*

ผลการศึกษา: *ผู้ป่วยชนิด C_2 พบบ่อย 59.6% ระยะเวลาติดตามผลการรักษาเฉลี่ย 25.2 เดือน ภาวะแทรกซ้อน พบการชาบริเวณเส้นเลือด 32.1% และชาชนิดถาวร 3.8% คุณภาพชีวิตพบว่าดีขึ้นหลังการรักษาจากคะแนน 32 ก่อนทำ หลังทำลดลงเป็น 24 คะแนน ถือว่าดีขึ้นอย่างมีนัยสำคัญทางสถิติ ($p<0.001$) อัตราเส้นเลือดดำอุดตัน 79.8% และอัตราการอุดตันบางส่วน และไม่พบมีการรั่วกลับของเลือดพบ 8.7%*

สรุป: *การรักษาเส้นเลือดดำที่ขาบกพร่องเรื้อรังโดยใช้คลื่นไมโครเวฟปลอดภัยและอาจเป็นทางเลือกหนึ่งในการรักษาโรคกลุ่มนี้ เพราะได้ผลดีในระยะยาว*