

ENDOVENOUS SAPHENOUS ABLATION USING EVRF RADIOFREQUENCY DEVICE AND CR45i CATHETER. EXPERIENCE OF 313 CASES.

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Introduction:

Radiofrequency ablation (RFA) is a medical procedure, where part of the electrical conduction system of the heart, tumor or other dysfunctional tissue is ablated using the heat generated from the high frequency alternating current. RFA has become increasingly accepted in the last 15 years with promising results.

Endovenous ablation has replaced stripping and ligation as the technique for elimination of saphenous vein reflux. One of the endovenous techniques is a radiofrequency based procedure. Newer methods of delivery of radiofrequency were introduced in 2007. Endovenous procedures are far less invasive than surgery and have lower complication rates. The procedure is well tolerated by the patients, and it produces good cosmetic results. Excellent clinical results are seen at 4-5 years, and the long-term efficacy of the procedure is now known with 10 years of experience.^{1,2}

The Belgian F care systems introduced EVRF for trans-dermal treatments 15 years ago and started its use for saphenous closure with the CR45i catheter in 2010. It works on 4 MHz and uses 25 Watts, which provides an effective closure of the vein trunks with minimal heat transfer to the surrounding tissues, causing minimal damage, no pain and providing an excellent closure rate.

Objective:

We evaluated the effectiveness of EVRF treatment and analyzed the early and middle-term results using the EVRF device with a CR45i catheter for the endovenous ablation of GSV and/or SSV.

Methods:

EVRF is a monopolar radiofrequency device, which works on 4 Mhz and delivers 25 Watts of continuous energy for endothermal saphenous ablation through the CR45i catheter. The surgical procedure is identical to other endothermal ablation methods: in a sterile operative field the treated main saphenous trunk (GSV and/or SSV) or greater tributary (i.e. anterior accessory vein) is punctured percutaneously and prepared by a 6 Fr sheath. The RF catheter is inserted and placed 2 cm below the saphenofemoral/sapheno-popliteal junction.³ Tumescent solution (in our cases: isotonic bicarbonate 1000 ml, 300 mg lidocaine and 0,5 mg epinephrine) is administered by ultrasound guidance.⁴ After double checking the catheter position at the cross the RF ablation starts: 25 Watts continuous energy is administered during a 6 sec/cm pullback of the CR451 catheter. The thermocoagulation property of the RF energy effects directly the vein wall, it results in shrinking and collapsing the target

vein, creating a fibrotic seal and occluding the vessel. The treated vein is immediately closed after the procedure, its diameter reduces continuously over time and becomes a fibrotic chord in about 6-12 months. 2-3 weeks of applying a class 2 compression stocking is the standard procedure after RFA, patients can return to normal activity in 1-2 days.

From July 16, 2011 to April 20, 2013 we treated 313 patients (99 men: 47 years of average age (range: 16-84 years) and 214 women: 49 years of average age (range: 26-79 years)) with saphenous reflux and varicosity of the GSV and/or SSV using the CR45i catheter of EVRF produced by F care systems. The output power was 25 Watts, the catheter withdrawal rate was 6 sec/cm with 12 sec/cm at the beginning, 2 cm back from the sapheno-femoral (sapheno-popliteal) junction. In every case we used tumescent local anesthesia (modified solution: isotonic bicarbonate 1000 ml, 300 mg lidocaine and 0,5 mg epinephrine) with superficial sedation if needed, in the present of an anesthesiologist.

Patients' clinical data, the data of the pre- and postoperative ultrasound examinations, the total power emitted and the diameters and flow of the treated veins measured by ultrasound have been recorded. Photo documentation was prepared in each case. Clinical evaluation was performed one day, one week, one to two months and one year after surgery using a scale of postoperative pain, VCSS clinical evaluation form, patient satisfaction and outcome ultrasound procedure.⁶

Results:

RF ablation were performed on 313 limbs - 268 GSV, 35 SSV, 10 GSV+SSV; 291 patients belonged to CEAP 2 or 3, 22 patients to CEAP 4 or 5; 274 primary cases, 39 recurrent varicosity. Crossectomy was performed in 6 cases due to the GSV larger than 20 mm at the junction. Tributaries were treated in the same session by microphlebectomy using a Varady phlebotomizer and hook in most of the cases or using foam sclerotherapy with 1 or 2 % polidocanol. The mean diameter of the GSV was 6,2 mm (range: 4-16 mm) and of the SSV 4,8 mm (range: 4-10 mm) consequently, reflux more than 0,5 sec was detected with duplex scan in all patients. The length of the treated vein segment was 45 cm in average (range: 15 to 82 cm), using an amount of 7200 Joules total energy emitted on average. The average duration of surgery was 48 minutes, including the treatment of the enlarged tributaries by microphlebectomy.

Complete occlusion was found in 275 of the 276 cases (99%) at the one month ultrasound control (until March 20, 2013), one GSV in a 160 kg heavy patient remained open. At one year follow-up 3 of 108 patients showed recanalization longer than 5 cm (97,2% 1 year occlusion) without clinical symptoms. At one year follow-up we evaluated the postoperative pain reported by the patients on a visual analogue scale (2,4 preoperatively, 1,2, 0,4 and 0,1 1 week, 1 month and 1 year postop respectively), the VCSS score (7,7 before surgery, 3,9 and 1,8 one month and one year respectively). The average patient satisfaction was 99%. There were no cases of deep vein thrombosis, skin burns, neuritis or bleeding, we found minimal bruising at the treatment site of the tributaries in some cases, 2 patient had mild inflammation, treatable conservatively.

Conclusion:

The EVRF saphenous ablation by using the CR45i catheter from F care systems is a safe, painless procedure for the treatment of the GSV and/or SSV - high patient acceptance and minimal postoperative discomfort allows the quick return to work and normal life. The procedure under local tumescent anesthesia is simple, the disposable devices are easy to use. In our practice the EVRF treatment with CR45i catheter was superior to conventional varicectomy or to laser ablation using a 810 nm diode laser with bare laser fiber. Further follow-up is planned.

Conflict of interest/Funding:

None.

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