

Pilot study

Treatment of varicose veins using thermal occlusion

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Introduction:

Primary varicose veins are one of the most common disorders in European population. Surgical intervention is considered to be the only preventive measure against complications, like e.g. the venously conditioned Ulcus cruris. Without adequate and duly carried out surgery, the course of this disease is rated to be progressive and incurable. This article describes the bipolar thermal occlusion with the Celon system as a new treatment method.

Aetiology:

Primary varicose veins arise due to vein wall weakness. It is thought that prolonged standing and sitting without regular exercise (e.g. on the job), several pregnancies, adiposity, chronic obstipation, hormonal anticonceptives and alcoholism might be the causes.

Pathogenesis:

Vein pressure increases, veins and valve commissures expand and cause a relative valve insufficiency of Vv. communicantes. This in turn leads to a retrograde transfer of pressure from the deep veins into the surface veins. With each contraction of muscles, blood from the depth is pressed to the surface and causes an expansion of veins. As a consequence, there will be myocyte proliferation and an increased fiber synthesis. The vein wall is strengthened but the single myocytes are separated and a metabolic coupling is inhibited. In the further course, fragmentation of elastic and collagen fibres can be observed leading to a weakening and aneurysm formation of the vein wall.

Indication for surgery is based on the clinical examination during which varicose expansion is diagnosed by inspection and palpation. In addition, colour-coded duplex sonography is carried out to assess the deep vein system, the V. saphena magna, the V. saphena parva and the perforating veins. Furthermore, postthrombotic syndromes must be excluded.

Grading of main varicose veins acc. to Hach:

- Stage I: insufficiency of the V. saphena magna at its junction with the femoral vein
- Stage II: stage I and varicose changes which go down to the knee joint-cavity
- Stage III: stages I and II and varicose changes which go down to a point approx. 5 cm below the knee
- Stage IV: stages I-III and finger thick changes which go down to the ankle

Clinical stages acc. to Marshall:

- Stage I: no discomforts, cosmetically disturbing
- Stage II: congestive feeling, cramps during the night, paraesthesiae
- Stage III: oedema, skin induration, pigmentation, healed ulcer cruris
- Stage IV: ulcer cruris venosum

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Material and methods:

In preoperative phase, tributaries are marked while the patient is standing.

After correct positioning of the patient, careful disinfection and sterile covering, the inguinal cut is made. Partly dull, partly sharp dissection and exposure of the hiatus saphenus. The afferent cross veins are being double ligated and then cut. Exposure of the V. saphena magna, grasping with two Overholt clamps and isolation. Firm proximal and distal ligation. Search for the magna vein after skin incision above the malleolus medialis; vein is then looped and a distal ligation is performed. Thereafter, incision of the venous lumen and insertion of the bipolar thermal probe (CelonProCurve 1200-S15, Celon AG medical instruments, Teltow) in proximal direction. Arrest of blood supply at 140 mmHg. Extirpation of the varicosely changed tributaries by the 'hook method (Varady)' through minimal cuts. Thermal occlusion is then carried out as follows: first, a value of 25 watts is adjusted on the power control unit (CelonLabPRECISION, Celon AG medical instruments). The thermal probe is then slowly withdrawn (approx. 1cm per second) from proximal to distal while applying radio frequency current. Audible presentation of the tissue impedance during the coagulation process enables a control of the movement rate. After-care of the cuts: disinfection and steri stripes. The distal incision is closed with an absorbable intracutaneous suture. Application of an elastic pressure bandage from distal to proximal. Release of blood pressure cuff. Closure of subcutaneous tissue in the groin region with interrupted over-and-over suture. Disinfection and closure of the skin with intracutaneous, interrupted over-and-over suture. Sterile bandage.

Results and discussion:

Compared to conventional methods, like the stripping of the V. saphena magna in toto, significantly less patients reported paraesthesiae, especially at 6 months. In the 'Weiss' study which covered 140 patients, paraesthesiae were observed in 8.5% (8.6% worldwide) at 1 week. At 6 months, the number of these patients decreased to 0.7% (5.7%). In the comparative study by 'Mackay', 25% of the patients who had undergone Zn stripping reported paraesthesiae at 2 weeks. At 6 months, the number of these patients decreased to 7.7%.

During the first postoperative ultrasound control at 1 week after treatment, it became apparent that 137 of the 140 legs were completely closed. At 6 weeks, reflux signals in the vein region were observed in 2 further patients. At 12 months, no changes compared with the previous findings were observed. 'Rautio' reported a recanalization in 26.7% and new tributaries in 10% of his patients. In the postoperative phase, 10% of the patients reported paraesthesiae and 3.3% skin changes. 'Weiss' patients, on the contrary, did not suffer from skin changes.

288 patients throughout the world suffered from minor skin burns which, however, could no longer be traced after another 6 months. Phlebitis occurred in 3.2% of the patients, but decreased to 2.2% at 6 months. In the preoperative phase, 85% of the patients reported pains and tired legs; but 2 years later, only 5% of the treated patients still suffered from these symptoms. Oedemas on the legs which, in preoperative phase, were observed in 19% of the patients did no longer occur at 2 years after treatment.

'Goldman' stated that at 24h after the respective operation his patients were able to do the same activities as in the preoperative phase and that no new varicose veins were observed at 3 resp. 6 months. On the course of the 'Lurie' study patients who had undergone thermal occlusion therapy were able to return to daily life activities after an average period of 1.15 days while the average time in the 'stripping' group was 3.89 days. Patients treated with obliteration were able to return to their jobs after 4.7 days while patients of the other group could return only after 12.4 days. 'Rautio' stated similar facts: patients with thermal occlusion therapy recovered faster from pains and weakness, their physical condition became stabilized within a shorter period of time and convalescence time was shorter as well. 'Navarro' reports a 100% closure rate. Within the first 7 days after treatment, mild ecchymoses and indurations were observed in the region where local anaesthetics were applied and/or the minimal phlebectomy was performed. None of the patients developed haematomae, infections, skin burns, paraesthesiae, thrombophlebitis, deep venous thrombosis, pulmonary embolism or allergic reactions. Patients were examined at an average period of 4.2 months after treatment. The results: no reflux signal was sonographically detected and none of the patients

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required further treatment. At 18 months, continued closure but there was 1 patient who suffered from slight pigmentation which, however, slowly healed up.

Up to now, 10 patients have taken part in the study on thermal occlusion in the Martin-Luther-Hospital. 2 patients had to change to the stripping method due to anatomic conditions. At 24 hours 1 patient reported wound pain and 3 patients developed discrete haematomae. Paraesthesiae, signs of infections or secondary bleeding were not observed. During follow-up at 8-12 days, discrete haematomae were observed in 3 patients. One female patient who was diagnosed with stage II acc. to Hach and had undergone an isolated cross-sectomy and thermal occlusion reported intense wound pain and showed moderate-to-severe haematomae at medial thigh. Sonographical follow-up showed complete closure of the V. saphena magna in 5 patients and in 1 patient there was a slight rest reflux in one segment. 1 patient had been treated with thermal occlusion only for varicose veins of stage II acc. to Hach and 2 patients did not attend the sonographical follow-up.

Conclusion:

In summary, it can be concluded that thermal occlusion is a gentle, effective and safe method for the treatment of varicose veins. This method offers distinct advantages over the conventional stripping method, especially with regard to postoperative discomforts. Mobility is achieved faster, patients report less pain and develop less haematomae. Recovery is significantly faster. A distinct palpable cord was observed in 1 patient only.

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