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Introduction
Endovenous radiofrequency-ablation, which is performed under tumescence-local anesthesia, was introduced in 1990, first in the USA and since then also in Europe. The first publications in regard to larger patient groups appeared in 2002.

Following this, endovenous laser therapy was established and both procedures are currently used in Switzerland. Long-term results are not available, but first studies have reported thrombosis formation in the deep vein system of the leg, which is undesirable in an electively performed intervention.

Advantages of endovenous therapies include the fact that invasiveness is minimal and patients are sooner mobile, reporting immediate return to everyday tasks. In particular, loss of working days is minimal.

At the general meeting of the Swiss Society of Phlebology in January 2005, it was decided to set up a central registry because of the lack of long-term follow-up data and the lack of data clarity concerning safety of method. The object of this registry is to record all thermic endovenous therapies carried out in Switzerland. This concerns endovenous laser therapy as well as endovenous radiofrequency-ablation. All members of the Swiss Society of Phlebology and those of the Swiss Society of Surgery were sent a questionnaire, asking them to participate in establishing this registry. A total of 22 practices and centers have replied.

Method

On the basis of a „Case Record Form“ (see supplement) the interventions and multiple follow-up examinations are to be documented as far as possible during the 5 years following the intervention.

To be stated is, on the one hand, the severity of chronic venous insufficiency, as well as the distension des Befalls of the veins to be treated, in terms of Hach.
Additionally, the diameter of the vein to be treated is to be measured in the Krosse area. In the Vena saphena magna region this would be the diameter immediately distal to the confluence of the Vena epigastrica superficialis and in the Vena saphena parva region the diameter preceding the deviation of the Vena femoro-poplitea, or if there is no Crosse, the diameter of the Parva stem at the crease level of the knee.

In regard to operation, laser therapy should state wave length, energy setting and energy density in joules per centimeter; radiofrequency-ablation should state apparatus setting and length of occluded segments.

Additionally performed treatments
Crossectomy, phlebectomy, sclerotherapy.

First Follow-up Examination:
One week after the intervention: clinical assessment concerning thrombosis in the deep veins of the leg and complete duplex sonographic clarification of the deep veins and calf muscle veins of the treated leg.

Second Follow-up Examination:
One year after the intervention: Duplex sonography of the treated segment. Assesssment as to whether occluded, partially occluded, or open. Clinical assessment by the patient and by the physician.

Further Follow-up Examinations
Every year after the intervention, if possible for 10 years: Duplex sonography of the segment that was treated. Assessment as to occluded, partially occluded, or open. Clinical assesssment by the patient and the physician.

For reasons of data confidentiality, the patients will be made anonymous: the second letter of the surname and first name will be used, date of birth, date of operation and dates of follow-up examinations. All questionnaires will be sent to a fax number or by letter to the center that records the central registry.

Data will be programmed using an Excel worksheet. Where there is lack of clarity, the person recording will contact the center concerned by telephone. Email connection can be set up on request; this lowers the guarantee, however, of data confidentiality.
Collected data is confidential in accordance with a corresponding separate agreement and may not be passed on. Any publication occurs only after consultation and after a general meeting of all the centers participating in the central registry.
The cost of secretarial work and programming will be assumed by the Swiss Society of Phlebology, the employer.
It is not intended that there be sponsoring by industry, particularly the companies which manufacture laser machines or radiofrequency-ablation machines.
It is planned that there be a meeting of the participating centers at least once a year to form an interim evaluation of the data received so far.

Statistics

The central registry is to record side effects at the first follow-up (especially any appearance of deep leg vein thrombosis). At the one-year follow-up and further follow-ups the percentage of occluded or re-opened vessels are to be recorded.
A patient group examined during the same time period at a center that does varicose vein operations will serve as control group.

Description of the Centers

The centers for thermic endovenous therapy represented in the central registry are to be recorded as to experience, that is, there will be a statement of the number of interventions carried out previous to the beginning of central registry recording. These centers commit themselves to reporting all performed endovenous interventions. The recording center, for its part, commits itself to confidentiality and to the protection of the patient-data entrusted to it. A corresponding contract will be signed with each participating center.

Agreement

The recording center commits itself to careful programming of the data sent in by the participating treatment centers. In addition it commits itself to confidentiality and will not publish data without consultation with all the participating centers. If any center is against publication of data, publication of the data will not be permitted. The primary goal of the central registry is to investigate the efficiency and safety of performed therapies. It is not primarily intended that a passing on
or application be made to Swissmedic regarding recognition as Tarmed achievement.

Questionnaire

Source (cohort). Please state your initials, only 1 name per center

Patient's name: initials

Patient's birthdate

Gender:
1 = female
2 = male

Side localisation
R = right
L = left
0 = none given

Date of intervention

Manner of intervention
Laser = L, VNUS = V

Laser energy

Diameter of treated vessel
2 = >0.5
1 = <0.5
0 = not examined

Diagnosis:
VSM Hach I – IV = M I-IV
VSP Hach I-III = P I-III

Leadvein insufficiency
1 = yes
2 = no
0 = not tested

Chronic venous insufficiency (CVI) at the time of intervention
1 = no (CEAP 1-3, Widmer <1)
2 = yes (CEAP 4-6, Widmer >2)
0 = not examined

Date of follow-up visit

Treated segment
3 = occluded
2 = partially occluded
1 = open
0 = no information

Thrombo-embolism, systematically searched for
2 = yes
1 = no
0 = no information

Indication of thrombo-embolism
(Dyspnoea, leg pain according to Wells – score)
2 = yes
1 = no
0 = no information

1 questionnaire for each leg treated
Please fill out one questionnaire for each patient and return immediately to:

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