LONG TERM FOLLOW-UP AFTER ENDOVENOUS LASER ABLATION

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Faculty Disclosure

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Endovenous laser procedure: our experience on 2452 patients from 2002 to 2013

- 2002: 810 nm laser + bare fiber: 42 pts
- 2003: 940 nm laser + bare fiber: 8 pts
- **2003-2008**: 980 nm laser + bare fiber: 1208 pts
- 2008-2011: 1470 nm laser + bare fiber: 174 pts
- 2008-2013: 1470 nm laser + radial fiber: 1020 pts
“Long term” results

• Long term results are related to clinical and echocolordoppler assessments obtained at least after a 5 years follow up period.

• Reports on long term results of endovenous laser ablation (EVL A) are rare, often retrospective and show very few patients evaluated at the end of follow up.
Bare fiberoptic and 980 nm laser (ELVeS-Biolitec AG) results. 6 years follow-up

• 209 consecutive patients treated between 2003 and 2004 and perspectively followed up for 6 years.

• 5 pts did not complete EVLA.
• Only 14 pts (6.8%) were lost for follow-up.
• 190 pts completed the planned 6 years follow-up period.

Six-year follow-up of endovenous laser ablation for great saphenous vein incompetence.

Demographics, clinical, surgical and echo-color-Doppler characteristics of the 190 patients who completed the 6-year follow-up period

- **Female gender**: 144 (76%)
- **Age (years), mean (SD; range)**
  51.5 (13.7; 21-90)
- **Body mass index (kg/m²), n (%)**
  - <24.9: 110 (58)
  - 25-29.9: 61 (32)
  - >30: 19 (10)
- **CEAP class, n (%)**
  - C2: 153 (81)
  - C3: 3 (2)
  - C4: 20 (11)
  - C5: 10 (5)
  - C6: 4 (2)
- **Vein treated, n (%)**
  - Great saphenous: 190 (100)
- **Great saphenous terminal valve, n (%)**
  - Incompetent: 171/190 (90)
  - Competent: 19/190 (10)
- **Crosse diameter (mm, (a)), mean (SD; range)**
  - 8.8 (2.3; 6-16)
- **Trunk diameter (mm), mean (SD; range)**
  - 7.1 (1.2; 6-12)
- **Refilling time, n (%)**
  - Normal (>25 seconds): 38/126 (30)
  - Abnormal (<25 seconds): 88/126 (70)
- **Laser variables**
  - Continuous mode, n (%) 190 (100)
  - Power (Watts), median (range) 10 (8-12)
  - Linear endovenous energy density (J/cm), mean (SD; range) **56.9** (11.7; 31-101)
  - Treated saphenous trunk (cm), mean (SD; range) 39.6 (8.9; 10-63)

_Crosse (a) Measured at 2 cm from the junction. SD, standard deviation._
Why did we choose echocolor Doppler failures (ECDF) as outcome?

- Clinical results (symptoms and varices) are very variable and therefore “weak” as outcome.
- Echocolor Doppler data are more standardizable and “consistent” than clinical ones.
- In a chronic progressive disease as varicose veins is, it is difficult to consider as good results a non occlusion or an incomplete occlusion of the trunk or the persistence of a leakage point, even though no recurrent varices or symptoms are present.
No significant correlation between ECDFs and clinical failures was observed

- Only 2 (9%), out of the 22 patients with clinical failures, had an ECDF.
- None of the patients with ECDFs initially had recurrent symptoms. Firstly varices recurred, often mild, and then when they worsened, rarely, also symptoms reappeared.
- Recurrent varices of the accessory anterior saphenous vein (AASV) have never been symptomatic.
Definition of echo-color-Doppler-confirmed failure

- **Best result:** competent junction and stump; occluded trunk along all the treated segment.
- **Failure:** refluxing junction and stump, isolated or associated with a reflux of one of its collateral, especially of the AASV or a recanalized saphenous trunk.
Bare fiberoptic and 980 nm laser results. 6 years follow-up

- **good clinical results:** 88.4% of pts with disappearance or improvement of symptoms.

- **mediocre duplex results:** 30% of suboptimal results:
  - recanalized saphenous trunk: 11.5%
  - reflux on the AASV of the thigh: 7.8%
  - isolated refluxing sapheno-femoral stump: 10.5%.

Kalpan-Meier plot of echo-color-Doppler-confirmed endovenous laser ablation failures.

Which ECDFs have required re-treatment?

• About half of the patients with ECDF of a refluxing AASV or of the saphenous trunk received ultrasound guided foam sclerotherapy due to recurrent varices or, more rarely, symptoms or to prevent recurrent varices.

• Isolated refluxing junction and stumps never required re-treatment. Therefore a question still remain: is this picture a sort of “normality” or a risk factor for a recurrence from the junction?
Multiple logistic regression analysis

the finding of

- an atypical crosse,
- a crosse diameter >8 mm,
- a mean trunk diameter >8 mm

is statistically significantly associated with echocolor doppler failures
• This study is a point of view on the "natural history" of EVLA and an "historical benchmark" to look at, in order to improve results with a reduction of ECDFs.

• Furthermore it has identified some patterns (and their frequency) of ECDF features typical of the endovenous laser treatments.
What did we learn from this study?

• Observation:
  – Good clinical results can be seen also in the presence of an ECDF

• Questions:
  – Can we consider really good a clinical result when an ECDF is diagnosed?
  – How long will last the good clinical results when there is an ECDF?
What did we learn from this study?

• **Timing of clinical recurrences:**
  – Refluxing AASV
    • Early varicose vein recurrence is frequent (within 1-2 years), without symptoms recurrence
  – Refluxing saphenous trunk
    • Late appearance of recurrent varices (after years) and even later recurrence of symptoms
  – Isolated refluxing junction and stump
    • No symptoms or varicose veins recurrence after 6 years
What did we learn from this study?

• Observation:
  – In the presence of an ECDF, recurrent varices or symptoms appears often many years after EVLA

Consequence:

• to evaluate the incidence of clinical recurrences we need a long/very long follow up (in literature there are very few papers with this kind of follow-up)
What did we learn from this study?

Question:
can we identify a “surrogate outcome” of clinical recurrence in the short/medium term to predict good clinical results in the long term?

My answer:
an echocolor doppler evaluation after 1-2 years might recognize the patients with sub-optimal results, to be treated with sclerotherapy or to be strictly followed up to prevent recurrences
What did we learn from this study?

- Observation:
  - A diameter of the crosse and of the trunk larger than 8 mm is a risk factor for ECDF
- Consequence:
  - it is important to collect these data preop. and to report them in the scientific papers
  - unfortunately, there is not a consensus on the methodology of measurement of these data
How can we improve the results?

- New Materials
  - 1470nm Laser
  - Radial fiber

- Technical Improvements
  - To give much more energy at the junction
  - To place the tip of the fiber below the origin of the AASV, when it is visible
  - To give energy to the saphenous trunk in relation to its diameter, following the “X 10 rule”
Radial fiberoptic and 1470 nm laser (ELVeS PL - Biolitec AG) duplex results. 3 years follow-up

- 174 consecutive patients treated between 2008 and 2009, prospectively followed up for 3 years.
- **Reduction of poor duplex results**: 8.6% vs 30%
- - no recanalization of the saphenous trunk: 0% vs 11.5%
- - no neovascularization below the refluxing stumps at the SFJ
- - reflux on AASV: 3.7% vs 7.8%
- - isolated refluxing saphenous femoral stump: 4.9% vs 10.5%