OBJECTIVES AND METHODS OF THE FOVELASS STUDY

This RCT aims to compare UGFS and EVLA in the treatment of insufficient SSVs ø≥4 mm

1. First endpoint: occlusion of the SSV (DUS SCAN) with a 3-year Follow-up
2. Secondary objective was to assess CLINICAL DATA (presence of varicose veins on SSV territory, DN4 questionnaire for neuropathic pain, satisfaction score, VCSS, CIVIQ-14)

12 Centres (same with several investigators)
Visits on D0, D8, M6, M12, M24 and M36

METHODS

SSV treatment:
- EVLA: 1470 nm Biolitec®, radial Fibre (600µ); strict TLA; only 1 session
- UGFS:
  - POLIDOCANOL (Aetoxisclérol®) Foam (1 vol. liq + 4 vol. air); 1 to 3% depending of the SSV diameter
  - In case of failure: 1 complementary session allowed at 6 weeks (D45)

In both groups, NO concomitant treatment of the tributaries was allowed, but at the FU visits, phlebectomies or sclerotherapy were possible (without retreatment of the trunk)

METHODS: UGFS BY DIRECT PUNCTURE WITH A NEEDLE

GENERAL DATA

161 patients included: 79 EVLA and 82 UGFS
- Both groups homogenous:
  - 73.6% female, mean age 59
  - a majority of C2b (53%)

- In the EVLA group:
  - Length of the treated venous segment (cm): 20.9 ± 5.1
  - Mean energy (joule per cm, LEED): 76.5 ± 10.5

- In the UGFS group:
  - Aetoxisclerol concentration (%): 1.5 ± 0.7
  - Volume of injected foam (cc): 3.0 ± 1.3
  - Complementary session at D45 only 3/82 patients (3.6%)
ANATOMICAL SSV DATA

<table>
<thead>
<tr>
<th></th>
<th>EVLA</th>
<th>UGFS</th>
<th>significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSV max diam (mm)</td>
<td>8.0</td>
<td>7.1</td>
<td>(4.5-15)</td>
</tr>
<tr>
<td>SSV mean diam (mm)</td>
<td>6</td>
<td>5.8</td>
<td>(4-11)</td>
</tr>
<tr>
<td>Presence of SPJ</td>
<td>Yes</td>
<td>Yes</td>
<td>94.8%</td>
</tr>
<tr>
<td>Distance SPJ to popliteal crease</td>
<td>20.6 mm</td>
<td>21.9 mm</td>
<td>N.S.</td>
</tr>
<tr>
<td>Cranial extension</td>
<td>Yes</td>
<td>Yes</td>
<td>36.4%</td>
</tr>
<tr>
<td>Giacomini vein</td>
<td>No</td>
<td>No</td>
<td>90.9%</td>
</tr>
<tr>
<td>Presence of variceous veins on SSV territory</td>
<td>Yes 92.2%</td>
<td>Yes 84.8%</td>
<td>N.S.</td>
</tr>
</tbody>
</table>

SYMPTOMS

- Pain
- Heavy legs
- Paresthesia
- Itching
- Restless legs syndrome

Almost all patients were symptomatic

DN4 QUESTIONNAIRE

(purpose for neuroathic pain)

SIDE EFFECTS

PRELIMINARY RESULTS (2-YEAR FOLLOW UP)

Before and after treatment: No positive score
**THROMBOTIC EVENTS**

In the UGFS group

- 5 medial gastrocnemius thromboses
- 1 thrombotic extension (EFIT)
- 1 non-occlusive extension to popliteal vein (EFIT) + thrombosis of lateral gastrocnemius veins (pain at D15).

Treatment: Rivaroxaban for 6 weeks + compression 30mmHg

DUS control at 5 weeks: popliteal vein completely recanalized; SSV occluded

In the EVLA group

- 1 medial gastrocnemius thrombosis
- 1 thrombosis of gastrocnemius, popliteal and femoral veins on D34.

Treatment: Rivaroxaban for 3 months + compression 30mmHg

DUS control at 1Y: deep veins completely recanalized; SSV fibrosed

3 symptomatic cases

**Complications depending on the centres**

<table>
<thead>
<tr>
<th>Case</th>
<th>Group</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>018</td>
<td>EVLA</td>
<td>EVLA GROSSESSE GROSSESSE</td>
</tr>
<tr>
<td>042</td>
<td>EVLA</td>
<td>EVLA THROMBOSE VEINEUSE PROFONDE POPLITEE GAUCHE + GASTROCNEMIENNES LATERALES DOULEUR FACE POSTERIEURE GENOU GAUCHE OEDEME RETRO MALLEOLAIRE EXTERNE GAUCHE</td>
</tr>
<tr>
<td>044</td>
<td>EVLA</td>
<td>EVLA TVP VEINES GASTROCNEMIENNES DOULEUR LEGERE MOLLET GAUCHE</td>
</tr>
<tr>
<td>063</td>
<td>UGFS</td>
<td>UGFS THROMBOSE VEINEUSE PROFONDE GASTROCNEMIENNE MEDIALE</td>
</tr>
<tr>
<td>107</td>
<td>UGFS</td>
<td>UGFS TVP GASTROCNEMIENNES MEDIALES PAS DE DOULEUR, PAS D’OEDEME, SEULEMENT DIAGNOSTIC ECHOGRAPHIQUE D’UNE TVP GASTROCNEMIENNE MEDIALE</td>
</tr>
<tr>
<td>127</td>
<td>UGFS</td>
<td>UGFS TVP GASTROCNEMIENNE MEDIALE GAUCHE DIAGNOSTIC UNIQUEMENT ECHOGRAPHIQUE D’UNE TVP GASTROCNEMIENNE MEDIALE</td>
</tr>
<tr>
<td>154</td>
<td>UGFS</td>
<td>UGFS TVP GASTROCNEMIENNE MEDIALE DROITE TVP GASTROCNEMIENNE MEDIALE DROITE</td>
</tr>
<tr>
<td>155</td>
<td>UGFS</td>
<td>UGFS TVP GASTROCNEMIENNE MEDIALE DROITE PAS DE SYMPTOMES</td>
</tr>
<tr>
<td>156</td>
<td>EVLA</td>
<td>EVLA TVP SURO-POPLITEO-FEMORALE SUPERFICIELLE GAUCHE SYMPTOMATIQUE</td>
</tr>
</tbody>
</table>
| 163  | UGFS  | EXTENSION THROMBOTIQUE (EFIT) DOULEURS PERSISTANTES SUITE A SCLEROSE AVEC EXTENSION FACE POSTERIEURE DE CUISSE EFFICACY RESULTS (DUS AND CLINICAL RESULTS) AT D8, 6 MONTHS, 1 YEAR AND AT 2 YEARS

**EFFICACY RESULTS**

(DUS AND CLINICAL RESULTS) AT D8, 6 MONTHS, 1 YEAR AND AT 2 YEARS

**DUS DATA**

Complete occlusion of SSV

Absence of a SSV reflux

**DUS DATA**

SSV DIAMETER

Length of vein occlusion (cm) for complete occlusion

UGFS group in the case of recanalisation (ie included in failures):
At 2 Y, mean diameter = 2.2 mm
A vast majority of patients became asymptomatic, with no significant difference between both groups.

**Asymptomatic patients**

<table>
<thead>
<tr>
<th></th>
<th>EVLA</th>
<th>UGFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>D0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>M6</td>
<td>73.8%</td>
<td>78.5%</td>
</tr>
<tr>
<td>1 Y</td>
<td>80.3%</td>
<td>85.4%</td>
</tr>
<tr>
<td>2 Y</td>
<td>68.6%</td>
<td>76.1%</td>
</tr>
</tbody>
</table>

The VCSS and QOL scores were highly improved in both groups, with no difference even at 2 years.

**VCSS**

- EVLA: 5.1% decrease from D0 to 1 Y
- UGFS: 73.8% decrease from D0 to 1 Y

**QOL**

- EVLA: 70.5% decrease from D0 to 1 Y
- UGFS: 81.4% decrease from D0 to 1 Y

**Group effect**: p=0.4491
**Time effect**: p<0.0001
**Interaction**: p=0.1551

**Presence of varicose veins (in the SSV region)**

<table>
<thead>
<tr>
<th></th>
<th>EVLA</th>
<th>UGFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>D0</td>
<td>92.3%</td>
<td>32.3%</td>
</tr>
<tr>
<td>M6</td>
<td>35.6%</td>
<td>24.6%</td>
</tr>
<tr>
<td>1 Y</td>
<td>26.2%</td>
<td>34.4%</td>
</tr>
<tr>
<td>2 Y</td>
<td>35.6%</td>
<td>34.4%</td>
</tr>
</tbody>
</table>

**Group effect**: p=0.1044
**Time effect**: p=0.2267
**Interaction**: p=0.1821

Only a few additional sclerotherapy treatments of tributaries were performed during the follow-up visits and NO phlebectomy was performed.

**Group effect**: p<0.0001
**Time effect**: p<0.0001
**Interaction**: p=0.3464

**Sclerotherapy M6 (n)**

- EVLA: 7
- UGFS: 11
- Total: 18

**Sclerotherapy 1 Y (n)**

- EVLA: 10
- UGFS: 7
- Total: 17

**Sclerotherapy 2 Y (n)**

- EVLA: 6
- UGFS: 15
- Total: 21

According to the literature and to these results, the first endpoint (occlusion rate) is questionable. Should we change it for further studies in the future?

**CONCLUSION**

Our preliminary results show that at 2-Year FU:
- the rate of occlusion of the SSV is lower for UGFS compared to EVLA
- but the clinical improvement is similar in both groups and remains stable over time

According to the literature and to these results, the first endpoint (occlusion rate) is questionable. Should we change it for further studies in the future?

**SPECIAL THANKS**

> F. A ALLEAERT AND MASSINISSA AROUN AND CENBIOTECH TEAM (STATISTICS)