Preliminary Data: 
HIFU For Venous Disease Treatment

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DISCLOSURES
THANKS TO THE ORGANIZERS FOR INVITING ME
- No financial interest
- No shares
- No consulting contract
- Study grant by Theraclion

General View of the HIFU SONOVEIN® Device

Visualization & Treatment Unit (VTU)

HIFU: a proven non invasive method for 2 common pathologies

- HIFU induces a shrinking process of the lesions within 2 years up to 99%
- Several thousands of cases treated since 2007
- Great experience in accurate targeting respectful of highly sensitive structures (trachea, carotid, recurrent nerve, esophagus, pleural structures, bones)

Proven clinical results: 25 peer-reviewed articles since 2014
3 ongoing FDA approved trials in US in Breast Cancer, Solid Tumors & BFA
SONOVEIN® on Insufficient Veins

Treatment set-up step - 2

- Planning of the treatment on touchscreen in longitudinal and transverse axes
- Treatment start

SONOVEIN® on Insufficient Veins

Example of hyper-echoic mark induced by tissue heating

Prospective Clinical Study on Insufficient Veins
Protocol synopsis

- Ethical approval in Austria
- To assess: feasibility, reflux abolition, safety and patient satisfaction, ease of use
- 50 legs treated:
  - 62%, (31/50): recurrent, 74% (33/50): C4 - C6
- Follow-up for 3 months
- Treated structures: Recurrences, Neovascularization at the stump, Perforators, GSV, AASV
- NO adjunctive methods (sclerotherapy, phlebectomy, ligation etc.) were performed at the moment of the intervention or during the 3 months follow-up period

Feasibility, Anesthesia, Tolerability and Safety Details

- For all selected patients the procedure was feasible
- Without any anesthesia in 17 cases (34%)
- No sedation or intravenous / oral medication
- No significant side effects such as skin changes, skin burns were present during and after the procedure. Very mild and transient dysesthesia was reported at early follow-up in four cases
- No thrombosis or PE, no anticoagulation medication

Example 1
Female, refluxing stump + neovascularization (high ligation), C1,2,3,4a

Before treatment

Before treatment

Collapsed stump, 4 sonication zones
Example 1
Female, refluxing stump + neovascularization (high ligation), C1,2,3,4a

Example 2
F, 70 yo, refluxing stump + neovascularization after surgery causing an ulcer, C1-C6

Example 3
Male, 95 yo, incompetent calf perforator, Ulcer, C1,2,3,4a,b,5,6

Example 3
Follow-up at M3
Inflammation and the pain resolved
Example 3
Male, 95 yo, incompetent calf perforator, Ulcer, C1,2,3,4a,b,5,6

Before treatment
Follow-up at M3
Perforator occluded

Example 3
Male, 95 yo, incompetent calf perforator, Ulcer, C1,2,3,4a,b,5,6

Before treatment
Follow-up at M3
Perforator occluded

Long term follow up example: GSV (left leg)
Treatment date: 20/06/2018.

Conclusion: Pro & Cons

Main Advantages
- Can treat over skin with severe atrophic disorders (ulcer)
- Extreme precision for the heat deposition
- No sterile field needed
- Can be performed without anesthesia or sedation at all
- Can treat very tortuous structures
- Safe procedure with a high level of patient satisfaction

Main Limitations
- Lack of long term studies
- Structures within 5 mm distance from the skin – may need subcutaneous infiltration