Comparison of the efficacy, safety, the primary and secondary technical success of the endovenous non-thermal, tumescensless mechanochemical ablation of varicose veins with the subjective outcome using different score-systems

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Disclosure

Speaker name: Christine Teichert

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

X I do not have any potential conflict of interest
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Background

• The most endovenous interventions for great (GSV) and small saphenous vein (SSV) insufficiency require thermal energy and instillation of tumescence anaesthesia

• MOCA is a tumescentless technique combining endovenous mechanical intimal injury with simultaneous infusion of a liquid sclerosans (polidocanol) to obliterate the veins

• MOCA has scientifically evidenced to be safe for the treatment of great saphenous vein insufficiency

Bishawi M et al. Mechanochemical ablation in patients with chronic venous disease: a prospective multicenter report, phlebology july 2014, vol 29 no.6, 397-400
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Objective

• The prospective study aimed to determine the quality of life and regard the development of pain in social sphere of life before and 6 weeks, 6 month and 1 year after an endovascular intervention on varicose veins compared to the technical success and concerning the development of secondary varicosis
Methods

• prospective study of consecutive patients, treated for GSV and SSV insufficiency with MOCA

• follow-up the improvement of the health-related quality of life using the modified version of the “Tübingen Questionnaire”, TLQ-CVI with 48 items

• group 1: 18 – 54 y
  group 2: 55 – 80 y

• clinical examination using the CEAP-Score and VDS

• Additional use of PDI to regard the development of pain and indeed duplex ultrasound before and after intervention, after 6 weeks, 6 month and 1 year
Patients inclusion criteria

- Gender: female, male
- Age: 18 – 80 years
- Patients with duplex proven venous insufficiency of the GSV or SSV (CVI > C2)
- great saphenous vein diameter: 5 - 17 mm
- small saphenous vein diameter: 3 - 10 mm
- Length of GSV or SSV incompetence: > 10 cm
- unilateral or bilateral GSV / SSV incompetence
- consent declaration of the patient
Patients exclusion criteria

- pregnancy
- acute thrombophlebitis
- acute deep venous thrombosis
- occluded deep venous system
- allergy or intolerance against Hydroxypolyaethoxydodecanol, Polyethylenglycol-Monododecylether (Polidocanol)
- CVI independent symptoms of the leg, eg. peripheral arterial disease, neuropathy, lymphedema
- known or suspected pulmonalarterial embolism
- coagulation disorder
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Treatment

• using the ClariVein catheter (Vascular Insights, USA) with Polidocanol under ultrasound guidance
• without tumescence anaesthesia
• without periinterventional antibiotics therapy
• periinterventional low molecular weight heparin
• post intervention compression stockings class III for 24 hours permanent followed by daytime wearing for 14 days
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Results

- 67 interventions on 52 patients (21m, 31f)
- 66 GSV und 1 SSV

1 year-results:
- 40 interventions on 26 patients (19m, 21f)
- group 1: 18 – 54 y – 21 patients
- group 2: 55 – 85 y – 19 patients
- 8/26 patients with Vein-stripping
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Ultrasound example:
66 years old woman, before MOCA
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1 year after MOCA
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- **periinterventional complications:**
  - 6/40 vein spasm
  - 1/40 system malfunction

- **postinterventional complications:**
  - hematoma: 7/40
  - Local phlebitis and pressure pain over the course: 7/40
  - No major- or minor complications
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Technical success:

• After 1 year: 36/40 (90%) obliteration

• 4/40 (all group 2!)
  - 2 patients open in the prox. segment (>4 cm)
  - 1 patient development of secondary varicose veins
  - 1 patient with right ventricular load – open
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CEAP classification:

- before: 6x C2, 26 x C3, 8x C4
- after 6 weeks: 3x C0, 20x C1, 13x C2, (2x C3, 2x C4)
- after 6 month: 3x C0, 21x C1, 12x C2 (3x C3, 1x C4)
- after 1 year: 3x C0, 21x C1, 12 x C2, (3x C3, 1x C4)
VDS (Venous Disability Score):

- before: 2x1, 26x2, 9x3, 3x4
- 1. post. day: 7x0, 32x1, 1x2
- after 6 weeks: 25x0, 14x1, 1x2
- after 6 month: 35x0, 4x1, 1x2
- after 1 year: 35x0, 4x1, 1x2
PDI – social activity (mean points):

- before: 3
- first post. day: 1.5
- after 6 weeks.: 0.5
- after 6 mon.: 0.4
- after 1 year: 0.3
• Results of QOL using vein insufficiency disease-specific questionnaire (modified version of the “Tübinger Questionnaire”, TLQ-CVI) with 48 items
<table>
<thead>
<tr>
<th>Item</th>
<th>Prepopulation</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Results</th>
<th>Postpopulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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MOCA-Study:
Results of QOL-questionnaire preinterventional

2000 questions
complaints on the legs (1-11)

- before: 83%
- after 6 weeks: 8%
- after 6 months: 10%
- after 1 year: 5%

preinterventional
- group 1: 81%, group 2: 84%
  - after 1 year:
    - group 1: 5%, group 2: 5%

- male 93%, female 77%
  - after 1 year:
    - male: 7%, female 4%

preinterventional
- group 1: 81%, group 2: 84%
  - after 1 year:
    - group 1: 5%, group 2: 5%

- male 93%, female 77%
  - after 1 year:
    - male: 7%, female 4%
discomfort because of CVI (12-15)

- before: 90 %
- after 6 weeks: 15 %
- after 6 month: 5%
- after 1 year: 5%

preinterventional
- group 1: 86%, group 2: 95%
- after 1 year:
  - group 1: 0%, group 2: 11%

preinterventional
- male: 100 %, female: 85%
- after 1 year:
  - male: 0%, female: 8%

total
improved comfort when standing (16-23)

- before: 53%
- after 6 weeks: 73%
- after 6 months: 85%
- after 1 year: 93%

preinterventional
- group 1: 52%, group 2: 53%
- after 1 year: group 1: 95%, group 2: 89%

preinterventional
- male: 43%, female: 58%
- after 1 year:
  - male: 93%, female: 92%
fears and worries (24-29)

- before: 78%
- after 6 weeks: 15%
- after 6 months: 15%
- after 1 year: 8%

preinterventional
- group 1: 57%, group 2: 100%
- after 1 year: group 1: 52%, group 2: 53%

preinterventional
- male: 57%, female 88%
- after 1 year: male: 43%, female: 58%
self-confidence (30-40)

- before: 13%
- after 6 weeks: 85%
- after 6 month: 85%
- after 1 year: 93%

preinterventional
- group 1: 5% (beauty?),
  group 2: 21%
- after 1 year:
  group 1: 100%, group 2: 84%

preinterventional
- male: 14%, female 12%
- after 1 year:
  male: 93%, female: 92%
sense of well being (41-42)

preinterventional
- group 1: 71%
- group 2: 58%

after 1 year:
- group 1: 100%
- group 2: 84%

preinterventional
- male: 64%, female 65%

after 1 year:
- male: 93%
- female: 92%
global satisfaction (43-48)

• before: 15%
• after 6 weeks: 83%
• after 6 months: 85%
• after 1 year: 93%

preinterventional
- group 1: 10%, group 2: 26%
- after 1 year:
  - group 1: 100%, group 2: 84%

preinterventional
- male: 0%, female 23%
- after 1 year:
  - male: 93%, female: 90%
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Conclusion

• MOCA is a safe treatment option for GSV- and SSV-insufficiency with a high technical success
• no severe adverse events, only minor side effects
• this intervention is able to improve the quality of life and reduce the pain in social sphere of life
• good clinical success with MOCA -100% occlusion in group 1 – early intervention important?
• MOCA needs no anesthesia
• short intervention time
Thank you
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