TREATMENT OF VARICOSE VEINS: CAN IT BE IMPROVED BY MECHANOCHIMICAL ABLATION USING THE CLARIVEIN DEVICE?

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Current ablative techniques

Need for tumescence
Risk for thermal injury
Postoperative pain
Hardware
Mechanochemical endovenous ablation – MOCA™

Mechanism of action:

- Combination: Mechanical damage + Sclerotherapy

- Mechanical: rotating wire $\rightarrow$ intimal / cellular damage and spasm of the vein

- Pharmacotherapy: sclerosans penetrates vessel wall $\rightarrow$ scar formation

- MOCA™ is NOT a variation on foam sclerosing
Mechanochemical endovenous ablation – MOCA™
MOCA™: The Clarivein® catheter

- 4 Fr. micropuncture sheath
- Small caliber catheter (2.7 Fr)
- Soft, flexible infusion catheter
- Rotating wire included in the catheter
- Bended tip facilitates catheterization
Initial trials – U.S.A.

- 30 GSV
- Sotradecol
- Mean diameter GSVs 8 mm
- Mean length GSVs 36 cm
- GSV treatment time 5 min
- Treatment time 14 min

Initial trials – U.S.A.

Obliteration

1 month: 30/30

6 months: 29/30

12 months: 20/20

3 patients with ecchymoses (side branches?)

Initial trials – Netherlands

- Polidocanol 1.5%
- 30 GSV in 25 patients
- M:F = 7:18
- GSV diameter 6.1 ±2.1 mm
- GSV length 40.0±6.6 cm
- Treatment time 20±4.8 min

Initial trials – Netherlands

- No nerve injury
- No DVT
- No skin injury
- No neurological or vision disturbances
- 9 (30%) minor haematoma
- 4 (13%) induration

Initial trials – Netherlands

- 6 weeks follow-up (n = 30)
- 29/30 (97%) obliterated
  - 1 recanalization
  - 3 patients proximal open segment (>4 cm) GSV
  - Anatomical success 87%
    - Fine tuning of technique
- VCSS: 3.0 (IQR 2.0-4.75) to 1.0 (IQR 0.25-3.0)
  - Improvement also in group with open proximal segment

Final results of Clarivein registry study

- Polidocanol 2.0% (2mL) and 1.5%
- 105 GSV
- 2 Dutch centers
- Primary endpoints
  - Anatomical success at 12 months
  - Clinical success at 12 months
- Secondary endpoints
  - Complications
  - QOL; SF-36 and AVVQ
Final results of Clarivein registry study

Inclusion criteria
- C2-C6
- Insufficient GSV
- Suitable for endovenous treatment (>3mm, tortuosity)
- Age > 18 years
- Signed informed consent

Exclusion criteria
- Vein > 12mm
- Pregnancy and lactation
- Allergy Polidocanol
- Previous treatment of ipsilateral leg
- History of deep venous thrombosis
- Use of anticoagulant
Final results of Clarivein registry study

- **M:F**: 3:7
- **CEAP**
  - C2: 37
  - C3: 36
  - C4: 34
  - C5: 32
  - C6: 2
- **VCSS**: 4 (IQR 3-5)
- **GSV diameter**: 6.0 ± 1.8 mm
- **GSV length**: 45 ± 8 cm
Final results of Clarivein registry study

- Treatment time: 11 ± 3 min
- Volume polidocanol: 5.4 ± 1.4 mL
- Complications:
  - No nerve injury, DVT, neurological or vision disturbances
  - 3 (3%) phlebitis
  - 8 (8%) minor hematoma
  - 11 (10%) induration
- Patient satisfaction: 8.8 ± 1.1
## Final results of Clarivein registry study

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<thead>
<tr>
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<th>6 months</th>
<th>12 months</th>
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<tbody>
<tr>
<td><strong>Clinical success</strong></td>
<td>94%</td>
<td>95%</td>
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<tr>
<td>• Improvement</td>
<td>94%</td>
<td>95%</td>
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<tr>
<td>• Deterioration</td>
<td>0%</td>
<td>1%</td>
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<tr>
<td>• Identical</td>
<td>6%</td>
<td>4%</td>
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<td>• VCSS 1 (IQR 0-2)</td>
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<td>VCSS 1 (IQR 0-1)</td>
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Final results of Clarivein registry study

6 months

- 102 patients
- Anatomical success 93%
  - 3 open GSV
  - 4 proximal open segment

12 months

- 100 patients
- Anatomical success 88%
  - 5 open GSV
  - 7 proximal open segment
Final results of Clarivein registry study

*Aberdeen Varicose Vein Questionnaire*

- Instrument which measures HR-QOL in patients with whole spectrum of venous disease (C1-C6)
  - Pre-operative: \(11.1 \text{ (IQR 8.1-19.0)}\)
  - One-year: \(2.2 \text{ (IQR 0.3-6.1)}\)
Postoperative pain and early QOL after MOCA™ and ClosureFast™ of incompetent GSV

- Non-randomised cohort study
- N=34 in each group
- Endpoints
  - Postoperative pain
  - Use of pain medication
  - Resumption of normal activities and work
  - VCSS
  - QOL (AVVO, RAND 36)

Postoperative pain and early QOL after MOCA™ and ClosureFast™ of incompetent GSV

- Complication rate, clinical outcome and postoperative QOL identical

- MOCA™:
  - Less postoperative pain
  - Less days of pain medication
  - Earlier resumption of normal activities
  - Earlier resumption of work

MOCA™ of the short saphenous vein

- Incidence sural nerve injury 1.3% - 11%
- First 50 consecutive patients
- Technical success 100%
- No major complications, especially no nerve injury or DVT
- 1-year anatomical success 94%
- VCSS
  - pre-treatment 3.0 (IQR 2-5)
  - 6 weeks 1.0 (IQR 1-3)
  - 1 year 1.0 (IQR 1-2)
  - P < 0.001

Duplex during follow-up

- Early postoperative period: no flow but often a compressible vein

- At 6 months: Vein is visible, but not compressible

- At 1 year: Vein often not visible anymore
Histology 1-year after MOCA™

- Circumferential disappearance of the endothelial layer
- Considerable damage to the tunica media in an inhomogeneous pattern
- The original lumen is organized with complex structure of collagen fibers and fibroblasts
Conclusions

- MOCA™ is a fast and safe technique for GSV and SSV insufficiency
- The early results are promising with acceptable closure rates
- MOCA™ is related to a very low incidence of major complications
- Learning curve, less forgiving than laser / RFA
Critical issues

- Polidocanol versus sotradecol
- Optimal dose and pull-back rate
- Long-term and comparative data
  - Maradona trial randomizing MOCA™ to ClosureFast™ for GSV insufficiency