Current Status of Non-Thermal/Non-Tumescent Saphenous Ablation

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Disclosure

Speaker name:
Thomas M. Proebstle

I have the following potential conflicts of interest to report:

☑ Consulting, Speaker Bureau
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
History of NT/NT saphenous Ablation

endovenous embolization of refluxing saphenous veins with

• polyglycolic acid yarn blocking device 2008
• mechanochemical ablation 2009
• cyanoacrylate glue (US or Turkish) 2010

generally

• no tumescent anesthesia
• no risk of paresthesia
• no compression stockings with CA glue
Methods

Device: Polyglycolic-Acid Yarn Implant

Hidden inside implant: Pushrod with nitinol release wire
Results Polyglycolic-Acid Yarn Implant

- Ultrasound appearance
- Side effects
- Occlusion rates
Polyglycolic-Acid Yarn Implant

Tahoe I:
2 weeks LMWH + eccentric compression

Tahoe II:
none
Table V. Post-Procedure Treatment Related Complications. NR = not recorded

<table>
<thead>
<tr>
<th>Side Effects</th>
<th>Day 1</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TAHOE I</td>
<td>TAHOE II</td>
<td>TAHOE I/II</td>
<td>TAHOE I</td>
</tr>
<tr>
<td>Erythema</td>
<td>10.2% (5/49)</td>
<td>6.7% (2/30)</td>
<td>8.9% (7/79)</td>
<td>11.8% (6/51)</td>
</tr>
<tr>
<td></td>
<td>2.0% (1/51)</td>
<td>6.7% (2/30)</td>
<td>3.7% (3/81)</td>
<td>11.8% (6/51)</td>
</tr>
<tr>
<td>Fever</td>
<td>NR</td>
<td>26.7% (8/30)</td>
<td>NR</td>
<td>34.5% (10/29)</td>
</tr>
<tr>
<td>Nausea</td>
<td>NR</td>
<td>33.3% (10/30)</td>
<td>NR</td>
<td>34.5% (10/29)</td>
</tr>
<tr>
<td>Thrombus extension into</td>
<td>NR</td>
<td>6.7% (2/30)</td>
<td>NR</td>
<td>10.3% (3/29)</td>
</tr>
<tr>
<td>CFV</td>
<td>0.0% (0/51)</td>
<td>10.0% (3/30)</td>
<td>3.7% (3/81)</td>
<td>19.6% (10/51)</td>
</tr>
<tr>
<td>Induration</td>
<td>0.0% (0/51)</td>
<td>10.0% (3/30)</td>
<td>3.7% (3/81)</td>
<td>19.6% (10/51)</td>
</tr>
<tr>
<td>Other</td>
<td>2.0%** (1/51)</td>
<td>3.3%* (1/30)</td>
<td>7.8%** (4/51)</td>
<td>6.9%* (2/29)</td>
</tr>
</tbody>
</table>

* Includes: “Patient fainted last night” at Day 1; “Bleeding” and “Inflammation and edema” at Week 1; “Episodes of hypotension” at Week 2
** Includes: Access point red/brown spot or Granuloma, Chilling, Fever, and Nausea
Methods

Device: Mechanochemical Ablation (MOCA)

Figure 1  Picture of the ClariVein® device
Mechanochemical Ablation (MOCA)

Limitations:

sclerosant dose limit of Polidocanol allows treatment of only one saphenous vein per session

Criticisms:

• no prospective randomized trials >12 months
• published 6 months FU ClosureFast vs Clarivein
• on the way: 12 months FU prospective randomized trials Laser vs Clarivein and CA vs Clarivein
Mechanochemical endovenous ablation of saphenous veins using the ClariVein: A systematic review.

Witte ME\(^1\), Zeebregts CJ\(^2\), de Borst GJ\(^3\), Reijnen MMPJ\(^1\), Boersma D\(^3,4\).

**Author information**

**Abstract**

Objective To systematically review all available English literature on mechanochemical endovenous ablation and to report on the anatomical, technical, and clinical success. Methods A systematic literature search was performed in PubMed, EMBASE, and the Cochrane Library on mechanochemical endovenous ablation for the treatment of insufficient great and/or small saphenous vein. Methodological quality of the included studies was evaluated using the MINORS score. The primary outcome measure was anatomical success, defined as closure of the treated vein on follow-up duplex ultrasound imaging. Secondary outcomes were technical and clinical success, and major complications defined as deep venous thrombosis, pulmonary embolisms or paresthesia. Results The literature search identified 759 records, of which 13 were included, describing 10 unique cohorts. A total of 1521 veins (1267 great saphenous vein and 254 small saphenous vein) were included, with cohort sizes ranging from 30 to 570 veins. The pooled anatomical success rate after short-term follow up was 92% (95\% CI 90-94%) (\(n = 1314\) veins). After 6 and 12 months these numbers were 92% (95\% CI 88-95%) (\(n = 284\)) and 91% (95\% CI 86-94%) (\(n = 228\)), respectively. The long-term anatomical success rates at 2 and 3 years were 91% (95\% CI 85-95%) (\(n = 136\)) and 87% (95\% CI 75-94%) (\(n = 48\)), respectively. Major complications and especially nerve injury were very rare (\(\leq 0.2\%\)). All studies were of
Methods
Clinical Studies with VenaSeal™ System

Feasibility Study
- 38 Patients, enrollment completed Aug. 2011
- 1, 3, 6, 12, 24 and 36 month follow-ups
- Primary endpoint: Safety: rate of serious adverse events, Efficacy: vein closure during follow-up

eSCOPE (European multicenter study)
- 70 patients, enrollment completed Sept. 2012
- 2 day, 1, 3, 6, 12, 24 and 36 month follow-ups
- Primary endpoint: closure w/o use of sedation, tumescent anesthesia or compression stockings

VeClose (U.S. pivotal trial)
- 242 patients, enrollment completed Sept. 2013
- 3 day, 1, 3, 6, 12 months & 2, 3 year follow-ups
- Primary endpoint: non-inferior to RFA in GSV closure
- Secondary endpoint: superiority in reduction of post procedural pain and bruising
One-Year-Follow-Up of The European Multicenter Study On Cyanoacrylate Embolization Of Incompetent Great Saphenous Veins

Principal Investigators:
for the eSCOPE Multicenter Study Group
Prof. Thomas M. Proebstle
University Medical Center, Mainz, Germany,
Privatklinik Proebstle, Mannheim, Germany
Prof. Alun Davies
Imperial College, London, United Kingdom

The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins

Objective: Cyanoacrylate (CA) embolization of refluxing great saphenous veins (GSVs) has been previously described. The outcomes from a multicenter study are still lacking.

Methods: A prospective multicenter study was conducted in seven centers in four European countries to abolish reflux by endovenous CA embolization. Neither tumescent anesthesia nor postoperative compression stockings were used. Varicose tributaries were treated until at least 3 months after the index treatment. Clinical examination, quality of life assessment, duplex ultrasound evaluation were performed at 2, 6, and 12 months. In 70 patients (68% of 102, 97.1%) were available for 12-month follow-up, 70 GSVs were treated. Two-day follow-up showed one proximal and one distal partial recanalization. Three additional proximal recanalizations were observed at 3-month (n = 2) and 6-month (n = 1) follow-up. Cumulative 12-month survival free from recanalization was 92.9% (95% confidence interval, 87.0%-99.1%). Mean (standard deviation) Venous Clinical Severity Score improved from 4.3 ± 2.3 at baseline to 1.1 ± 1.3 at 12 months. Aberdeen Varicose Vein Questionnaire score showed an improvement from 16.3 at baseline to 6.7 at 12 months (P < .0001). Side effects were generally mild; a phlebitic reaction occurred in eight cases (11.4%) with a median duration of 6.5 days (range, 2-12 days). Pain without a phlebitic reaction was observed in five patients (8.6%) for a median duration of 1 day (range, 0-12 days). No serious adverse event occurred. Paresthesia was not observed.

Conclusions: Endovenous CA embolization of refluxing GSVs is safe and effective without the use of tumescent anesthesia or compression stockings. (J Vasc Surg: Venous and Lym Dis 2015;3:2-7.)
Most Highly Cited Article

San Diego, June 3rd 2017:
The Most Highly Cited Paper Award of the Soc Vasc Surg / JVS for
One Year Results of the European Multicenter Cohort Study

most Highly Cited Paper
also in 2017
VenaSeal™ Closure System vs. Radiofrequency Ablation for incompetent Great Saphenous Veins

VeClose Study 36-Month Results

Principal Investigator:
Nick Morrison, Phoenix, AZ, USA

Comparison of cyanoacrylate closure and radiofrequency ablation for the treatment of incompetent great saphenous veins: 36-Month outcomes of the VeClose randomized controlled trial.
Morrison N, Kolluri R, Vasquez M, Madsen M, Jones A, Gibson K.
## Title
VenaSeal™ Closure System vs. Radiofrequency Ablation for Incompetent Great Saphenous Veins

## Purpose
Demonstrate the safety and effectiveness of the VenaSeal™ closure system for the treatment of lower extremity truncal reflux compared to RFA (ClosureFAST™ system).

## Study Design
**US multi-center, randomized controlled IDE study.** The study takes a non-inferiority approach to effectiveness for anatomical closure at 3 months. 24 months effectiveness assessed and compared across groups.

## Enrollment / Sites
242 (20 roll-in and 222 randomized) subjects enrolled at 10 study sites (Sep 2013).

## Follow-up
Follow-up visits at 3 days post-procedure, 1, 3, 6, 12, 24 and 36 months.

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Primary endpoint
COMPLETE CLOSURE

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>VenaSeal (N=108)</th>
<th>RFA (N=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 3</td>
<td>100% (108)</td>
<td>99.1% (114)</td>
</tr>
<tr>
<td>Month 1</td>
<td>100% (105)</td>
<td>87.3% (110)</td>
</tr>
<tr>
<td>Month 3*</td>
<td>99% (104)</td>
<td>95.4% (108)</td>
</tr>
<tr>
<td>Month 6</td>
<td>99% (101)</td>
<td>96.2% (105)</td>
</tr>
<tr>
<td>Month 12</td>
<td>96.8% (95)</td>
<td>95.9% (97)</td>
</tr>
<tr>
<td>Month 24</td>
<td>95.3% (86)</td>
<td>94% (84)</td>
</tr>
<tr>
<td>Month 36</td>
<td>94.4% (72)</td>
<td>91.9% (74)</td>
</tr>
</tbody>
</table>

94.4% closure rate, demonstrating long term durability at 36 months; and continued non-inferiority results to RFA (P=0.005) through 36 months.
36 Month - Venous Clinical Severity Score (VCSS)

VCSS: an evaluative instrument that is responsive to changes in disease severity over time and in response to treatment.

36 Month Results
- VenaSeal: VS 1.25 ± 1.60
- RFA: 1.69 ± 2.42
- p-value = 0.5643*

*Morrison, N. VenaSeal Closure System vs. Radiofrequency Ablation for Incompetent Great Saphenous Veins (VeClose). 36 Month Results presented at: IVC; April 20, 2017; Miami, Fl.
A Randomised Clinical Trial Comparing N-Butyl Cyanoacrylate, Radiofrequency Ablation and Endovenous Laser Ablation for the Treatment of Superficial Venous Incompetence: Two Year Follow up Results.

Eroglu E1, Yasim A2.

Abstract

OBJECTIVE: To compare early and two year results for N-butyl cyanoacrylate (NBCA), radiofrequency ablation (RFA), and endovenous laser ablation (EVLA) in the treatment of varicose veins.

METHODS: This was a randomised clinical trial. Five hundred and twenty five patients were blindly randomised into NBCA, RFA, and EVLT groups (175 patients to each group; block randomisation using sealed envelopes). Four hundred and fifty six patients were monitored for 2 years (ultrasound at 2 days, and 6, 12, and 24 months). The primary endpoint was the saphenous vein occlusion rates, and the secondary endpoints were peri- and post-procedural pain, complications, and time to return to work. No simultaneous phlebectomies were performed.

RESULTS: The numbers of patients lost to follow up were NBCA seven, RFA 26, and EVLA 36. Occlusion rates were similar at 6, 12, and 24 months (6 months [NBCA 98.1%, RFA 94.1%, and EVLA 95.1%, p = .14], 1 year [NBCA 94.7%, RFA 92.5%, and EVLA 94.2%, p = .72], 2 years [NBCA 92.6%, RFA 90.9%, and EVLA 91.5%, p = .89]). Peri-procedural pain was significantly lower after NBCA (p < .001), but complication rates (DVT, bleeding, and phlebitis) were similar. Time to return to work was shortest after NBCA (NBCA 1.04 days, RFA 1.56 days and EVLA 1.31 days (p < .001) with 95% (NBCA), 50% (RFA) and 75% (EVLA) of patients returning to work on Day 1. Pre-procedural venous clinical severity scores (VCSSs) were the same in all groups. A decrease was observed in VCSS values in all groups at 6 months, and this persisted at 1 and 2 years. However, VCSS scores at 6 months and 2 years were significantly lower in the NBCA group (p < .001). Foam sclerotherapy was subsequently applied to varicose tributaries in 18 patients from all groups.

CONCLUSION: No differences were observed in occlusion rates between the three modalities, but NBCA appeared superior with respect to peri-procedural pain, return to work and decreased VCSS.
Conclusion

Endovenous embolization of saphenous veins with cyanoacrylate has become a routine treatment in the US and Europe.

MOCA shows good short term results as well, but currently no randomized trial with FU of more than 6 months published.