Venclose™

clinical experience with a new radiofrequency ablation catheter
Disclosure

Speaker name: Anina Lukhaup

I have the following potential conflicts of interest to report:

- [x] Consulting Pfizer, Bayer, Daiichi Sankyo
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)
- [ ] I do not have any potential conflict of interest
Radiofrequency ablation

- Non-surgical, catheter-based thermal ablation
- Gentle alternative to surgical treatment
- Safe, efficant, easy to perform
- 1998 Closure plus (VNUS™), ClosureFast 2006 (Covidien™), renamed Venefit (Medtronic™)
- Further development?
Venclose™ - What’s new?
Venclose™ - What’s new?

• One catheter to ablate both 2.5cm and 10cm vein segments
• 6 Fr less invasive, smaller access incision
• Slightly bowed tip for ease of navigation
• Single line 2.5cm and double line 10cm interval shaft markings for precise repositioning
Flexible and steerable catheter tip

* catheter tip

Foto Dr. Thierjung
Precise power output

The Venclose digiRF™ displays power output in Watts per cm of heating element. User sees a standardized unit value whether 2.5cm or 10cm is selected.
Treatment time

Comparison of in-vein time treatment of an average 40cm GSV with Venclose 10 cm and Medtronic 7 cm heating elements

- 30% less in-vein ablation / repositioning time

<table>
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<th>Reposition</th>
<th>2nd 6.5cm</th>
<th>Reposition</th>
<th>3rd 6.5cm</th>
<th>Reposition</th>
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<tbody>
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<td>5 secs</td>
<td>1 x 20 secs</td>
<td>5 secs</td>
<td>1 x 20 secs</td>
<td>5 secs</td>
<td>1 x 20 secs</td>
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</tbody>
</table>
Venclose™ versus ClosureFast™

• Single center, open-label, retrospective review 100 closureFast procedures and 100 venclose procedures
• Efficacy equivalent
• No statistical difference in complication rates
• 30% shorter ablation time – results in 30 seconds

Shao, M. et al., ACP Nov 2019 poster presentation
EU Post Market Clinical Follow-Up Study of the Venclose System

- Prospective, non-randomised, single center study (Leipzig)
- Non-inferiority study
- Primary endpoints: closure rate and freedom from recurrence at 3, 6, and 12 months
- Secondary endpoint: venous insufficiency measured by CEAP classification and VCSS at 3, 6, and 12 months after treatment
Conclusion

• New radiofrequency ablation catheter
• Advantages to the established catheter system
  • More flexible
  • Changeable heating tip length
• Time saving of no practical use in daily routine
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