Summary of Thermal Ablation RCTs

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Disclosures

• None

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Collected RCTs on operative treatment of CVD since 1990 (surgery, chemical and thermal ablation)

• Today total 186 RCTs
• 84 RCTs involve thermal ablation
• Phlebolymphology.org
• Full documentation with abstracts
• Important source of information

• Do we need further RCTs?

Systematic reviews and metaanalyses increasingly important in evidence based medicine

• The development well described by Gurevitch in Nature 2018; 555: 175 - 82
• Critizised by Ioannidis : The mass production of redundant, misleading and conflicted systematic reviews and meta-analyses. Milbank Q 2016; 94: 485 - 914

Common sense a good principle when you try to understand meta-analyses

• Do most studies point in the same direction?
• Is the effect significant?
• Are the patient-related outcome measures relevant?
• What happens if you exclude one study?

Available meta-analyses

• 2008 Luebke, Germany
• 2009 van den Bos, The Netherlands
• 2012 Siribumwong, Thailand
• 2014 Nesbit, Cochran, UK
• 2017 Hamann, The Netherlands
• 2018 Rass, Germany
• 2018 Kheirelseid, Ireland
The Irish: Systematic review and meta-analysis of RCTs evaluating long-term outcomes of endovenous management of lower extremity varicose veins

- JVS-VL March 2018; 6: 256-270
- 9 RCTs comparing conventional surgery and endovenous therapy with 5 years or more FU were selected
- Available for EVLT, RFA and UGFS
- Primary outcome was recurrence rate detected clinically or by duplex

Results concerning recurrence rate

- No significant difference in EVLT vs surgery
- Same for RFA vs surgery
- Same for RFA vs EVLT
- Inferiority of UGFS vs EVLT and surgery with 4 times higher risk of recurrence and double risk of re-intervention

Their conclusions

- The quality of evidence poor
- Therefore more trials that are well powered to examine long-term outcomes are warranted

The new kids on the block steam, MOCA and Venaseal are not included in the meta-analyses due to lack of > 5 years FU

Obsolete RCT’s

- Endovenous laser in the presented long-term RCTs were performed by 810-980 nm wavelength using a bare fiber
- There is a paucity of RCTs comparing open surgery with novel endovenous laser (higher wavelength, radial fiber) and new RF techniques

Recent criticism against endovenous ablation

Is the pendulum swinging towards high ligation and stripping again?
Reconsidering the endovenous revolution
Olle Nelzén, BJS 2016;103

- Neovascularization dominant finding following HLS
- Proximal saphenous stumps and incompetent anterior accessory saphenous veins (AASVs) main factor after EVA
- Long-term FU suggests that the recurrence rate after EVA seem to increase over time

Summary of needs for further RCTs

- Quality of present RCTs poor in several meta-analyses
- No thermal endovenous technique is superior to open surgery
- RCTs rapidly obsolete due to change in technology
- More trials that are well powered to examine long-term outcomes are warranted

Final point

- Apparently we need more RCTs to satisfy the quality requirements for clinically important systematic reviews and meta-analyses
- And what about the clinical guidelines?? SVS/AVF, EVF, ESVS, NICE?

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- A substantial number of patients who have undergone EVA will eventually develop symptomatic recurrence requiring repeat tx
- Such scenario would change the equation regarding patient benefit and costs making EVA less competitive and challenging current guidelines
- HLS still seems to be a good long-term alternative calling existing guidelines into question