Non-thermal endovenous technologies have “comparable” outcomes to those achieved with thermal technologies at one year

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Non-thermal, non-tumescent technologies to treat varicose veins were shown to have comparable short-term outcomes to those obtained with thermal technologies at the recent Charing Cross Symposium (28 April–1 May, London, UK).

There is a vast array of technologies that can be used in the treatment of varicose veins including several thermal and non-thermal technologies. The important thing is not which the most appropriate treatment is, because very good results are achieved by using several of these, but “the key is getting the right patients treated, getting the right reimbursement, and that is what we should focus on,” the panel noted. The discussion also revealed that the most important long-term endpoints were quality of life coupled with intervention rates. Further, the treatment of tributaries was highlighted as a way of reducing recurrence after thermal ablations and many experts said that concomitant phlebectomies were the way to improve outcomes for these technologies.

While non-thermal technologies often emphasise that tumescent anaesthesia is not a requirement—a factor that confers a clear benefit because it is less painful for patients in the short-term—some presentations suggested that the outcomes of foam sclerotherapy, a non-thermal technology, can be improved by the addition of tumescence. This provided a contradiction of sorts: while some experts believed that the addition of tumescence to non-thermal technologies bettered outcomes and was justified because patients forget about the pain from tumescent anaesthesia, others noted that they would find the addition of tumescence to a non-thermal technology to be “a suboptimal solution”. Overall, the presentations provided delegates with the most important developments in both thermal and non-thermal technologies.

**Thermal techniques: Radiofrequency ablation**

Olivier Pichot, Grenoble, France, presented five-year data using the ClosureFast (Venefit) 7cm catheter system. Venefit is a sequential procedure with two cycles, at the termination of the greater saphenous vein (GSV). Echoguidance is mandatory at each step of the procedure: vein access, catheterisation, positioning and tumescent anaesthesia. The ClosureFast study was conducted between April 2006 and March 2007. The investigators treated 295 limbs in 225 patients at eight centres in Europe. Most of the patients were females (74.9%) and most of them presented with CEAP clinical class 2 or 3. All veins treated were great saphenous veins.

The early results showed technical success in all legs, and immediate occlusion was achieved in all patients, except one (99.7%) who presented delayed occlusion detected at three-month follow-up. Vein wall thickening was observed in all patients.

At five years, the study was completed with 78.7% of the patients (236 legs in 177 patients), and the investigators observed great saphenous vein occlusion in 91.9% of the patients. In addition, 94.9% of patients were free from reflux. The great saphenous vein diameter, measured 3cm below the saphenous femoral junction, decreased from 5.8mm before treatment to 1.4mm at five years follow-up.

*In terms of anatomical failure during follow-up, we observed GSV blood flow in 25 patients, and reflux was presented in 15 of them. With regards to CEAP time course, between one year and three years varicose veins reappeared and we saw an incidence of more than 30% of patients at five years.*

*At five years, the Venous Clinical Severity Score (VCSS) decreased from 3.9 to 1.3. Complications and side effects were mild. At five years, only one patient presented with residual paraphaesthesia.*

*We demonstrated the radiofrequency ablation with the Venefit procedure is efficient, safe and increases significantly immediate postoperative comfort for the patients. The five-year follow-up study demonstrates high durability of the once achieved great saphenous vein occlusion, and sustained improvement of clinical symptoms at long-term follow-up,* Pichot said.

**Bipolar radiofrequency ablation**

Isaac Nyamekye, Worcester, UK, then spoke on the benefits of bipolar radiofrequency technology. During
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...bipolar radiofrequency induced thermotherapy (RFITT, Olympus) the energy is delivered from the Celon Precision generator through the ProCurve applicator with its bipolar tip and there is an isolated segment between the two metallic parts defining the bipolarity.

“There are no randomised trials comparing the radiofrequency devices currently and we are undertaking such a trial at the moment. The Trial of Radiofrequency Thermo-ablation Treatments of Great Saphenous Varicose Veins is randomising patients to Venefit, RFITT or EVRF. Follow-up is by visual pain scores, duplex ultrasound assessment and quality of life questionnaires. The primary outcome is six-month ablation, and patients will be followed up with questionnaires at 12 months and hopefully, beyond,” he said.

“In the absence of randomised data we looked at our results with the three devices in a retrospective study from our prospectively maintained database. Patients were matched for age, sex, vein length and diameter. We found that RFITT (5.4sec/cm) and Venefit (6.7sec/cm) took a significantly shorter time to perform than the monopolar device (9.1sec/cm). RFITT and Venefit also produced 100% truncal ablation at six weeks compared to 90% for the monopolar device. However, at the time the study was being performed it was the original monopolar setup that was being used, without a neutral pad electrode. We have noted that with the addition of the neutral pad electrode the monopolar device is better in terms of efficacy and this is being used in our randomised trial,” he explained.

Current published evidence comes mainly from series data. Early publications showed that Venefit had ablations from 94% to 97% compared to 89% for RFITT. But in 2013, Braithwaite and his group published a paper showing 92% ablation at six months for the RFITT system. “This was for a large selection of operators with varying degrees of experience. In a subgroup in which operators had good experience using RFITT, they showed 98% ablation. We reported our data last year (Newman et al) also showing 98% ablation using the to and fro method. So RFITT can produce effective ablation in experienced hands,” Nyamekye concluded.

Monopolar radiofrequency—the EVRF system

Attila Szabo, Budapest, Hungary, reported that the monopolar radiofrequency system, EVRF (F Care Systems), provided high closure rates, and was easy to use, with the flexible 0.5cm catheter allowing treatment of more complex anatomies. “The device is multitalented as we can treat small, medium and large veins with the same device,” he noted. EVRF is not only for truncal veins but also for middle-size and large veins. The system has choice of different disposables adjusted to the size of the veins, Szabo explained.

According to a study of EVRF for small veins conducted by Jean Marc Chardonneau, the percentage of recovery varies from 70% to 95% depending on the treated site. For mid-size veins, there is a small diameter catheter that can be inserted into the vein to apply local anaesthesia to treat these superficial veins from 1–4mm. It is also possible to treat smaller tributaries with this catheter.

“In our experience, we have treated 751 patients (73% females) between July 2011 and March 2015. Patient characteristics were very similar to those seen in other experiences with endovenous ablation devices. We had a 99% occlusion rate at one month, 97.2% at one year and 96.8% at three years. Patient satisfaction was high, pain scores were low, and quality of life improved after one month and one year,” Szabo added.

Laser

Ian Chetter, Hull, UK, then examined new laser fibre technologies including jacket, tulip and radial fibres to state that the modifications in the fibres had resulted in maintaining efficacy (occlusion rates) and reducing the energy density required. This resulted in reduced bruising and pain, he noted.

MOCA comes of age

Alun Davies, London, UK, kicked off the section on non-thermal, non-tumescent techniques by making the case for mechanochemical ablation (MOCA) having come of age. MOCA (Clarivein, Vascular Insights) combines mechanical endothelial damage using a rotating wire with the infusion of a liquid sclerosant. Heating of the vein and tumescent anaesthesia are not required and only local anaesthesia is utilised at the insertion site. Davies outlined the ideal endovenous device as one that provides a 100% occlusion rate, 100% patient satisfaction and durable results over a five to 10-year time horizon. “By this definition, we do not have the ideal device as yet,” he maintained.

Davies emphasised that the 2013 UK National Institute for Health and Care Excellence (NICE) guidelines recommended a clear treatment hierarchy of endovenous thermal ablation that was followed by foam, and then followed by surgery. Similar recommendations came from the American Venous Forum with respect to clinical assessment, investigation and treatment hierarchy. In the UK, NICE has MOCA on a special measures, or interim regulatory arrangement before it can go on to become a fully recognised treatment, he said.

On the point of tumescent anaesthesia, Davies said: ‘You have inflicted pain on your patients if you have used...
tumescent anaesthesia. Obviously, the simplest non-thermal non-tumescent technology is foam sclerotherapy. If you make your own foam in the UK, it is inordinately inexpensive. There are also more expensive technologies such as Varithena (BTG),” he added.

Davies then showed a slide with data showing that the Clarivein device had been used in over 600 limbs and had shown high occlusion rates with no major adverse events.

He then alluded to the multicentre, randomised trial comparing mechanochemical to radiofrequency ablation: the Venefit vs. Clarivein for varicose veins (VVCVV) trial. The primary outcome was pain during ablative procedure (but before tributary treatment) and the results showed that maximum pain was significantly less in MOCA compared to radiofrequency early on. “By the time you get to six weeks, the quality of life data and occlusion data are the same,” he noted. He further outlined that MOCA and glue were showing comparable short-term outcomes to radiofrequency or laser at one year with similar quality of life improvement and over 90% occlusion rates, which is comparable to any thermal techniques.

Davies noted that while laser and radiofrequency had a risk of thermal damage to nerves, skin, surrounding tissue and paresthesia, Clarivein and VenaSeal did not. Similarly, Clarivein/VenaSeal do not require multiple injections of tumescent anaesthesia. “With regard to anatomical suitability, radiofrequency and laser are for GSV and small saphenous vein (SSV), but are not ideal for SSV due to nerve thermal damage. Clarivein and VenaSeal are suitable for GSV, SSV and small veins down to the ankles.

“We do not have the ideal device as yet. [...] None of these have a 100% patient satisfaction, 100% occlusion rate and 100% improvement in quality of life. But yes, MOCA has come of age and is a comparable technology to thermal techniques,” Davies concluded.

**Variclose glue**

Kursat Bozkurt, Istanbul, Turkey, presented on glue ablation with Variclose (Bio las). He noted that the overall experience in Turkey, from over 200 centres, shows that 8,000 cases have been performed in 14 months and that the initial experience with the technology is good. “More long-term data with glue are needed,” Bozkurt said.

He further added that since the endovenous programme begun in March 2005, there was now full reimbursement for endovenous procedures in the last five years. Bozkurt added that while the results obtained with current thermal techniques are good, the requirement of tumescent anaesthesia results in substantial post-interventional discomfort.

Glue is used to treat great saphenous vein insufficiency and small saphenous vein insufficiency. Bozkurt went on to provide the results of the Turkish multicentre study of 181 patients with an average Venous Clinical Severity Score (VCSS) was 4.99±1.15 at baseline. The average length of the treated vein segment was 31.62±6.09cm. The results showed a 100% procedural occlusion rate. At the six-month follow-up, there was no total recanalisation observed. There were, however, five partial recanalisation observed and the total occlusion rate was 97.23%.

Further, there was postoperative pain in 11 patients (6.07%) and five patients had phlebitis (2.76%). There was no venous thromboembolism and the average VCSS improved from 4.98±1.15 at baseline to 1.39±0.8 at six months.

Citing the advantages of using Variclose, Bozkurt noted that it was a continuous procedure with no need for tumescent anaesthesia. “Cyanocrylate is easy to use compared to thermal ablation techniques and it eliminates nerve damage caused by thermal ablation. There is no need for the use of compression stockings; there are no skin lesions or burn marks after treatment; no need for operating room conditions and patients can return to work and daily routines immediately,” he concluded.

**VenaSeal closure system**

Guido Lengfellner, Regensburg, Germany, then reported on the use of cyanocrylate with the VenaSeal closure System (Medtronic) for the treatment of refluxing great saphenous vein. The system gained the CE mark in 2011 and FDA approval in 2015.

Lengfellner made the point that typical cyanocrylate was very brittle and hard after polymerisation. It has a low viscosity that means it moves easily can cause non-target embolisation and is slow to polymerise, he noted. However, VenaSeal is a formulated cyanocrylate for venous application; it is soft and flexible after polymerisation and has a high viscosity so that it can be well controlled and fast polymerisation (30 seconds) upon contact with blood so there is no risk on non-target embolisation.

Alluding to the evidence available to back the use of the system, Lengfellner emphasised the feasibility study that showed a three-year, 94.7% closure rate and the US pivotal, prospective, randomised trial VeClose, that demonstrated the safety and effectiveness of VenaSeal by showing non-inferiority at three months to radiofrequency using ClosureFast. The trial demonstrated a 98.9% closure rate at six months.

Lengfellner also discussed the findings of the European multicentre study eSCOPE that set out to evaluate the safety, efficacy of VenaSeal for the treatment of refluxing GSV. The primary endpoint is duplex ultrasound closure without use of sedation, tumescent anaesthesia or compression stockings and the study showed closure rates at six months of 94.3% and at one year of 92.9%.

Speaking with regard to his own experience he highlighted that there is great advantage to the absence of tumescence in that the procedure was almost painless, although “Some patients had some minor pain in the first days after the intervention.”
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Alun Davies, Attilio Cavezzi and Kursat Boskurt

Foam sclerotherapy
Attilio Cavezzi, San Benedetto del Tronto, Italy, presented on ways to improve the outcomes of foam sclerotherapy. “Foam sclerotherapy has proved to be effective, especially in terms of quality of life and we are obtaining similar results as with laser and radiofrequency at one and three years, but not with regard to occlusion rates. Since the beginning of our experience, we realised that blood was a problem for foam sclerotherapy. So we started to propose a couple of methods to improve the way we deliver foam and the way foam impacts the vein wall.”

Cavezzi and colleagues proposed that the usage of a long catheter, ultrasound-guided tumescence infiltration also in foam sclerotherapy and saphenous irrigation prior to foam delivery seem to improve the outcomes.

He referred to data from a recent study from his group showing that clinical recurrence after foam sclerotherapy was 6% when no tumescence was used; it was 6% when tumescence was used with visual estimation, but no ultrasound-guidance and was 0% when ultrasound-guided tumescence was used. There was a significantly higher occlusion rate as determined by duplex ultrasound when ultrasound-guided tumescence was used when compared to the group in whom no tumescence was used. Further, there were significantly higher occlusions in the ultrasound-guided tumescence group when compared to the group receiving tumescence under visual estimation. “It seems that tumescence works,” he said.

A combination of catheter foam sclerotherapy of the saphenous trunk including peri-saphenous tumescence infiltration and saphenous irrigation, with concomitant phlebectomy of the varicose tributaries was shown to achieve clinical recurrence rates of 0% at one, six, 12 and 18 months. At one and six months, the occlusion rate was 100%. Later at 12 and 18 months, it was 93.6% and 86.6%, respectively. There were four recanalised GSV and two showing reflux after 18 months as determined by duplex ultrasound, Cavezzi said.

Foam phlebectomy
Michael Cummings, St Louis, USA, spoke about the techniques and outcomes of foam phlebectomy.

Synchronised ablation and phlebectomy have been shown to improve early quality of life and have prolonged improvement in clinical status. By far and large, this is preferred by patients, Cummings noted.

“We see that foam sclerotherapy is fast, safe and effective, and on the downside associated with painful lumps, staining and potential embolic phenomena. On the other hand, ambulatory phlebectomy is safe, effective and has no lumps, but is time consuming, associated with more patient discomfort and is not necessarily appropriate for all veins,” Cummings explained.

“Why not combine both and create a foam phlebectomy? An advantage would be the ability to treat a complete range of varicosities and avoid the limitations of either procedure, with some concern of spillage of foam into the soft tissues. It turns out that there are some unexpected advantages such as better sclerotherapy, potentially safer sclerotherapy, easier phlebectomy and fewer bleeding problems,” he said.

With foam and tumescence, we get compressed veins, better wall contact and less foam is needed for the procedure and that can be removed after it has time to dwell, Cummings explained.

“Foam phlebectomy offers better foam sclerotherapy due to better wall contact, use of less foam, removal of foam and needs less microphlebectomy. It also offers a better ambulatory phlebectomy because you can use ultrasound guidance for difficult varicosities, and if you do miss a vein during phlebectomy, it can be treated ultrasound-guided foam sclerotherapy and there is less bleeding,” he said.