Issue 3

Venous Times

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Reporting the latest news regarding venous diseases, conditions and treatments

ATTRACT: Building awareness through clinical research

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1470nm laser reduces pain and anaesthesia use

Presenting data at the recent American Venous Forum meeting in Phoenix, AZ, Dr Jose I Almeida, Director, Miami Vein Center, Voluntary Associate Professor of Surgery, University of Miami, FL, reported the outcomes from a study that examined whether the 1470nm wavelength could be achieved with less energy – and therefore less heat production, less perforation, less pain and bruising – could closure be accomplished without anaesthesia.

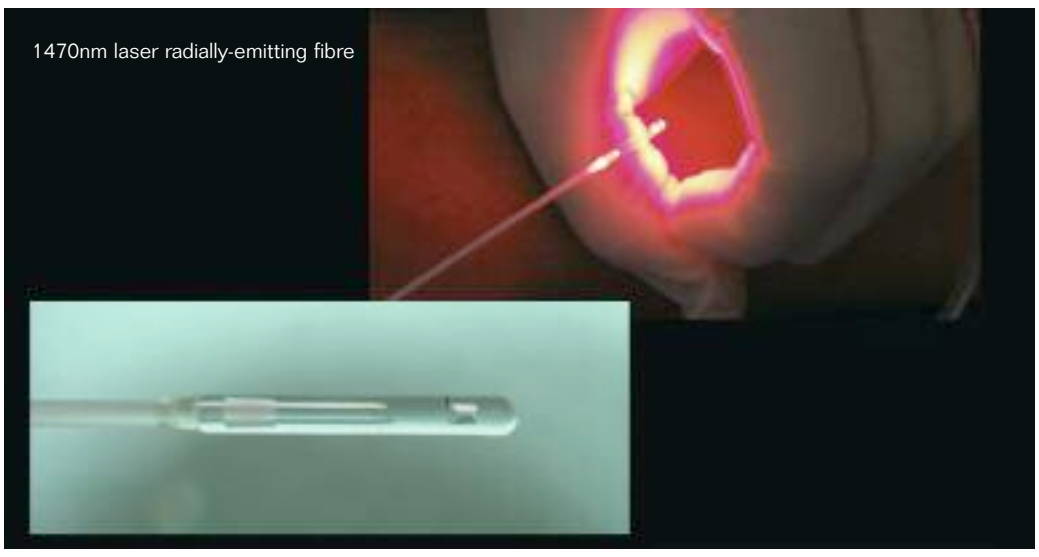
Although there are many benefits that are gained from utilising endovenous lasers, it has been reported in literature that direct fibre contact causes coagulation, vapourisation and carbonisation of tissue (perforation)[1], leading to post-operative pain and bruising. Furthermore, research has also shown that more pain and ecchymoses seem to be associated with the laser treatments at 940nm compared with 1320nm.

The reason for this apparent reduction in side effects after endovenous laser closure is due to differences in the target chromophore in the blood vessel. The 940nm laser light is absorbed primarily by haemoglobin, which causes rapid heating of the vessel and vessel-wall perforation. Whereas the 1320nm laser light is absorbed primarily by water, which is believed to heat the vessel more gradually and uniformly, leading to vessel-wall coagulation and less frequent perforation[2]. *In vitro* research by Dr Walter Cecchetti indicated that the1470nm laser was 40 times more absorbable in water and demonstrated a four-fold increase in vapourisation, compared with the 980nm laser.

The study investigated the safety, efficacy and side effects of the 1470nm laser (Biolitec) using various protocols and investigate whether the 1470nm wavelength can close a saphenous vein painlessly, by using lower energy densities, in the absence of perivenous anaesthesia. The formal manuscript has been accepted for publication in *Vascular and Endovascular Surgery*.

Methods

Twenty-six limbs were treated in the Dominican Republic with a radially-emitting fibre at low energy ranging from 20J/cm at 3 watts, to 30J/cm at 5 watts. Perivenous anesthesia was used selectively and titrated to patient comfort. Then 41 veins were treated with the 1470nm laser at 30J/cm at 5 watts using standard perivenous tumescent anaesthesia in Miami. Miami patients were compared to a historical control treated with the 980nm wavelength at 12 watts, 80J/cm.



1470nm laser radially-emitting fibre

Results

Thermal ablation using the 1470nm at low energy densities were not tolerated without the addition of a perivenous anaesthetic. A protocol of 30J/cm at 5 watts delivered satisfactory procedure speed, 100% primary closure in the short-term, and minimal side-effects. Fewer side effects were produced by the 1470nm laser versus a 980nm historical control. Patients treated with perivenous tumescent anaesthesia trended toward a better experience and better outcomes than patients with perivenous local anaesthesia added selectively.

Conclusion

Almeida said that by employing a radial-firing 1470nm laser it was possible to reduce the delivered energy from 60–80J/cm to less than 30J/cm by more laser-specific targeting of the vein wall. Small amounts of local anaesthesia were still required for analgesia. "The primary closure rate (87.5%) for cases done with less than 30J/cm and without the tumescent technique is lower than current thermal ablation benchmarks, but respectable." In comparison, at one-month there was closure in 100% of patients in both the Miami and Control Groups using a more traditional tumescent technique, because the tumescent fluid allowed the target (vein wall) to be brought into closer proximity to the energy source (laser fibre tip)," he added.

Jose Almeida

He claimed more histological information is needed to examine vein wall changes induced by 1470nm at low energy, and recommended that a randomised controlled trial be performed to truly determine the closure rate and side effect differences between the 980nm and 1470nm wavelengths.

References

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EVF in Copenhagen 2009

Niels Bækgaard
President elect EVF
Chairman of the organising committee

It is a great honour to have the 10th meeting of European Venous Forum in a Nordic country. In a time with increasing interest and focus for venous disease worldwide, it has been challenging to create a program with the best speakers heading the very "hot issues" in time. As usual, the meeting combines sessions with invited speakers and free selected papers.

Thirty six papers were chosen from 70 submitted papers. This year we have introduced a short paper session consisting of six short presentations of five minutes with five minutes for discussion. The selection was done by a prominent committee. The free papers are a crucial fundament for EVF. In this way venous research is stimulated to present the latest results. As usually, there will be a prize for the three best papers.

A symposium under guidance of the Scandinavian Venous Forum will begin the meeting. Some Nordic centres have been leaders in the understanding and treatment of diseases in the deep venous system. The presenters will highlight the mechanism and formation of oedema in CVI, treatment for primary and secondary valve insufficiency and acute and chronic occlusions with endovenous procedures.

A session will focus the alternative treatment for varicose veins. Are there any improvements in the open surgery? What are the contraindications and pitfalls for the new endovenous methods? The most experienced doctors will take part in the discussions based on presented examples.

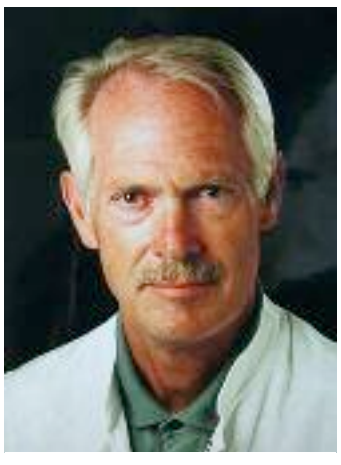
The newest development for anticoagulation will be addressed in a following session. Clinical validation of the safety and efficacy of anti-Xa and Anti-IIa. Are they really superior?

How to address and present venous papers will be discussed. The ideal can not always be presented, but a basic knowledge can provide a better understanding and enable presenters to improve their presentation skills.

EVF has invited a prominent speaker from USA to address the most important field these years: local thrombolysis for deep venous thrombosis, and new mechanical devices have emerged to facilitate this concept. A real breakthrough can spare a lot of patients from often disabling complications, if late durability can be achieved.

Four prize winners, two from the AVF and two from EVF, will present their work at the end of the meeting.

Hopefully there will be lot of good discussions in the audience in a friendly atmosphere during the meeting, which is a fundamental quality in the European Venous Forum. With this meeting, the organising committee certainly hopes to maintain a central position for EVF among the other venous fora in the world.



Niels Bækgaard

VenUS II: Larval therapy benefits debridement

The first outcomes from the larval therapy for leg ulcers (VenUS II) clinical trial have shown that although larval therapy did not improve the rate of healing of sloughy or necrotic leg ulcers or reduce bacterial load compared with hydrogel, it did significantly reduce the time to debridement and increase ulcer pain. Furthermore, in a cost effectiveness analysis from the trial, the researchers reported that debridement of sloughy or necrotic leg ulcers with larval therapy have similar costs to treatment with hydrogel.

Non-healing leg ulcers are common, costly to the NHS and distressing for patients. Many leg ulcers contain slough and necrotic tissue and, whilst is widely thought to contribute to healing, there is no level one evidence to support this theory. Larval therapy has been proposed as a quick and effective debridement strategy and is increasingly used in the NHS, primarily by nurses. It is believed that the use of larval therapy allows for the production of enzymes that liquefies dead tissue, as well as ingesting and digesting bacteria.

It has been proposed that larval therapy may achieve debridement more swiftly than modern wound dressings, which promote a moist environment aiding self debridement, and, unlike surgical debridement, larval therapy use is not reliant on highly trained personnel or the fitness of the patient for surgery. An additional benefit of larval therapy is the removal of wound bacteria and Methicillin-Resistant Staphylococcus Aureas (MRSA), however, any robust evidence of this is limited.

Study design

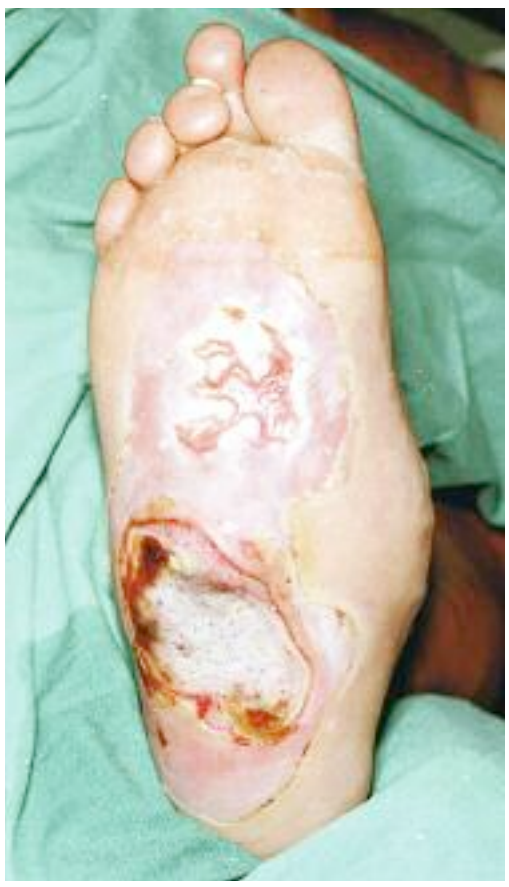
As a result the VenUS II randomised, clinical trial was designed to assess the impact of larval therapy on wound microbiology, including MRSA, and the acceptability of the treatment for patients. In addition, the study was assigned to establish the cost effectiveness of larval therapy in the healing of venous and mixed arterial/venous leg ulcers.

The trial compared the clinical effectiveness of larval therapy with a standard debridement technique (hydrogel) for sloughy or necrotic leg ulcers. Funded by the Health Technology Assessment Programme, patients were randomly allocated to receive one of the following treatments: loose larvae (n=94); bagged larvae (n=94); or hydrogel (n=87).

The study enrolled 267 patients with at least one venous or mixed venous and arterial ulcer with at least 25% coverage of slough or necrotic tissue, and an ankle brachial pressure index of 0.6 or more. The primary outcome was time to healing of the largest eligible ulcer. Secondary outcomes were time to debridement, health related quality of life (SF-12), bacterial load, presence of MRSA, adverse events, ulcer related pain (visual analogue scale, from 0mm for no pain to 150mm for worst pain imaginable), effective use of health service resources and quality of life.

Results

The results showed that time to healing was not significantly different between the loose or bagged larvae group and the hydrogel group (hazard ratio for healing using larvae vs. hydrogel 1.13, 95% confidence interval 0.76 to 1.68; p=0.54). Larval therapy significantly reduced the time to debridement (2.31, 1.65 to 3.2; p<0.001). Health related quality of life and change in bacterial load over time were not significantly different between the groups. A total of 6.7% of participants had MRSA at baseline, but no difference was found between larval therapy and hydrogel in their ability to eradicate MRSA by the end of the debridement phase (75% (9/12) vs. 50% (3/6); p=0.34), although this comparison was underpowered.



Ulcer

Mean ulcer related pain scores were higher in either larvae group compared with hydrogel (mean difference in pain score: loose larvae vs. hydrogel 46.74 (95% confidence interval 32.44 to 61.04), p<0.001; bagged larvae vs. hydrogel 38.58 (23.46 to 53.70), p<0.001.

Cost effectiveness analysis

The cost effectiveness and cost utility analyses was carried out alongside the multi-centre trial, with a main outcome measure expressed in terms of incremental costs per ulcer-free day (cost effectiveness analysis) and incremental costs per quality adjusted life years (cost utility analysis).

On average, the treatment cost with larval therapy was £96.70 (€109.61; US$140.57) more per participant per year (95% confidence interval – £491.9 to £685.8) than treatment with hydrogel. The incremental cost effectiveness ratio for the base case analysis was estimated at £8,826 per quality-adjusted life years gained (annual difference 0.011) and £40 per ulcer-free day. Considerable uncertainty surrounds the outcome estimates.

Conclusion

The researchers conclude from these findings that 'larval therapy did not improve the rate of healing of sloughy or necrotic leg ulcers or reduce bacterial load compared with hydrogel, but did reduce the time to debridement and increase ulcer pain'.

The cost effectiveness and cost utility analyses carried out alongside this study concluded that 'debridement of sloughy or necrotic leg ulcers with larval therapy is likely to produce similar health benefits and have similar costs to treatment with hydrogel'.

WINNER OF BEST PAPER AT 2009 UK VENOUS FORUM MEETING, LONDON

Post-procedure pain, safety and efficacy following great saphenous (GSV) endovenous laser ablation (EVLA) using a 1470nm diode laser

Anna Ikponmwosa[1], *Rosie Darwood*[1], *Michael Gough*[1], *Michael Gaunt*[2]

1 Leeds Vascular Institute and
2 Addenbrookes Hospital, Cambridge

Endovenous laser ablation (EVLA) is a promising minimally invasive treatment with recent studies confirming short term results comparable to surgery.

It is a safe procedure and serious complications are rare. However a significant number of patients experience post-procedure pain and bruising with phlebitis occurring in up to 30%.[1]

Although the technique and components of procedure are becoming standardised, there is considerable variation in the laser wavelengths used. There are few studies comparing wavelengths however, those published indicate there may be less bruising and a lower requirement for analgesia in those treated with longer wavelengths.[2,3]

A possible explanation for the improved results is related to the absorbance profile of haemoglobin and intra cellular water. The wavelength of the current generation of laser (810–980nm) mainly target haemoglobin whereas longer wavelengths are absorbed up to forty-fold more by water, potentially producing greater tissue penetration.

The aim of this study was to ascertain whether laser wavelength influenced outcome post EVLA for truncal vein incompetence.

Methods

A prospective study was performed in patients with primary varicose veins secondary to great saphenous vein reflux. Those suitable for EVLA underwent consultant led treatment using either an 810 (Group A) or 1470nm (Group B) continuous diode laser. In out-patients, under local anaesthetic, the GSV was cannulated under ultrasound guidance. The guide wire was placed and the catheter tip advanced to within 1–2cm of the sapheno-femoral junction. All patients received tumescent anaesthesia. The laser fibre was then inserted into the catheter and slowly withdrawn, delivering continuous laser energy at a rate of 2mm/sec, aiming to deliver a minimum of 60J/cm.

Upon completion a foam sponge was positioned over the vein and compression bandage applied for one week followed by a further week of compression stockings. During the first week patients completed 100mm visual analogue scale for pain assessment on a daily basis.

At six weeks post-procedure patients were clinically examined for evidence of complications and underwent ultrasound scanning at that point and a further scan at three months in order to identify abolition of GSV reflux.

The primary end points were therefore pain score and GSV occlusion. Statistical analysis was performed using SPSS version 16.0.0 (Statistical package for Social Sciences Inc, Chicago, Illinois, USA). A p value ≤0.05 was considered statistically significant.

Results

Forty-nine patients were included in the study with two patients having received bilateral treatment.

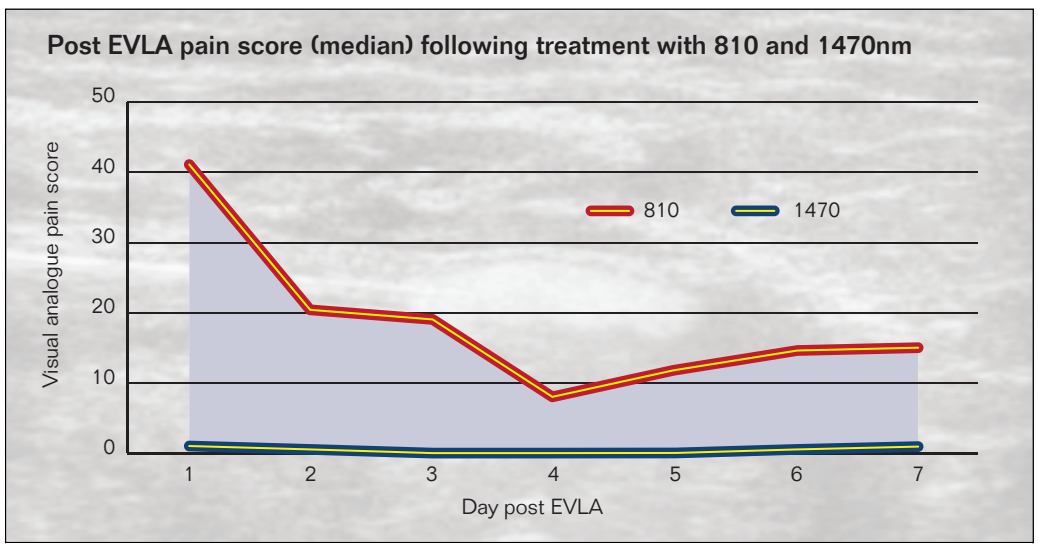


Figure 1: Pain score post EVLA

Mike Gough

There were more women in the study but there was no significant male female ratio difference between the two groups (p=0.378 Chi square test).

The median age was 53 and patients treated had a CEAP score between two and five.

Both groups received median laser energy of 70J/cm. Group B had a 100% occlusion rate whilst in group A there was one failure to cannulate the GSV and two patients had a partially occluded GSV resulting in a 90% occlusion rate.

Two patients in group A suffered transient saphenous paraesthesia and a further three had phlebitis. There were no complications in group B.

Significantly lower pain scores were reported by patients treated with 1470nm (Figure 1).

Conclusion

The results of this study confirm previous anecdotal reports that longer wavelength lasers are associated with less post-procedural pain than those currently used for EVLA.

Furthermore there were no complications in the 1470 group confirming its safety and all veins were successfully occluded.

These results would be consistent with the hypothesis that the energy from the longer wavelength laser specifically targets the vein wall rather than causing thrombotic occlusion superimposed on irreversible vessel damage.

A randomised control trial is being developed in order to confirm these apparent benefits.

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