

Digital Metronomes and Metric Devices for Venous Ablation Procedures

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ABSTRACT Ultrasound-guided endovenous ablation procedures have revolutionized the care of patients with venous reflux disease for more than a decade. Precise application of energy forms and substances that occlude superficial truncal veins is pivotal for technical success. Exact spatial and temporal delivery of ablative vectors to the vein is operator dependent, readily measurable, and hinges on precise timing of pullback of the various catheters and fibers that effect vein ablation. Several physical and online electronic pullback timing aids, including metronomes and other metric devices, are available to ensure precise ablation, although operators are often left to discover them. Although these are not ultrasound devices per se, they are essential adjuncts for the effective delivery of a key ultrasound-guided intervention and are used in direct proximity to ultrasound. To the authors' knowledge, there are no publications regarding this key ablation step, which is typically dependent on operator resourcefulness.

Introduction

Ultrasound-guided endovenous ablation procedures have revolutionized the care of patients with venous reflux disease for more than a decade.¹ Precise application of energy forms and substances that occlude superficial truncal veins is pivotal for technical success. Exact spatial and temporal delivery of ablative vectors to the vein is operator dependent, readily measurable, and hinges on precise timing of pullback of the various catheters and fibers that effect vein ablation. Several physical and online electronic pullback timing aids, including metronomes and other metric devices, are available to ensure precise ablation, although operators are often left to discover them. Although these are not ultrasound devices per se, they are essential adjuncts for the effective delivery of a key ultrasound-guided intervention and are used in direct proximity to ultrasound. To the authors' knowledge, there are no publications regarding this key ablation step, which is typically dependent on operator resourcefulness.

Background and Rationale

The endovenous revolution in phlebology occurred when new vein catheter techniques delivering various types of occlusive energy sources intersected with the advancing applications of ultrasound assessment of

venous form and function. New gold standards in the treatment of venous reflux include the thermal ablation techniques endovenous laser ablation (EVLA, various manufacturers and wavelengths) and radiofrequency ablation (RFA, various manufacturers). Ultrasound plays a pivotal role in diagnosis, patient selection, intraprocedural guidance, and postprocedural follow-up for safety and efficacy.

Emerging and next-generation techniques that are expected to match the exceptional efficacy of EVLA and RFA while improving the side effect profile as well as broadening applicability include ClariVein mechanochemical occlusion/embolization (Vascular Insights, LLC, Madison, CT),² Steam Vein Sclerosis (CermaVein, Archamps, France), and Cyanoacrylate Glue VenaSeal ablation (Sapheon, Inc., Santa Rosa, CA). All depend on accurate catheter withdrawal pullback rates while applying the specific vein closure energy form or substance. For EVLA, it is widely accepted that the prime determinant of efficacy and safety is the amount of thermal energy deposited per centimeter of vein, known as linear endovenous energy density (LEED).^{3,4} Optimal occlusion rates correlate with LEED of 60–90 J/cm. LEED is routinely calculated immediately after the procedure using the vein length and energy displayed by the laser console. Lower LEED values are associated with vein patency; greater values are associated with phlebitis, perforation, pain, and bruising. LEED is the product of laser power (J/sec, in Watts) and pullback rate (sec/cm). Because the power is preselected, user independent, and constant, pullback rate determines LEED and clinical success. Accurate pullback timing is thus at the crux of the procedure and carries the weaknesses of being user dependent, variable, and is usually left to the operator's devices.

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Discussion

Metronomes and Other Metric Devices

Several devices are available to effect accurate and variable pullback rates. Variables include mechanical, electronic, virtual/computerized, auditory, visual, temporal, spatial, and onboard energy dosimetry features. Prices range from free to hundreds of U.S. dollars.

The simplest are the centuries-old mechanical metronomes, with variable speeds and chimes. Some laser consoles (e.g., Vari-Lase, Vascular Solutions, Inc., Minneapolis, MN) have onboard audio tones and visual real-time displays of energy deposition, which can enable accurate pullback rates. One has a mechanical pullback system attached to the fiber (CTEV, CoolTouch, Inc., Roseville, CA). However, many consoles do not have onboard tones, including the large number of older systems still used. In addition, newer ablation catheters such as ClariVein and VenaSeal have as one of their advantages their lack of expensive energy generator sources and are thus free-standing catheter systems, also dependent on accurate pullback rates and without onboard cues.

When we began performing EVLA ablation, we used crude timing techniques, including watching a clock (requiring averting gaze from the sheath) or having an assistant call out seconds (subject to fatigue and distraction). Our laser (D15+, Angiodynamics, Latham, NY) provided only visual time countdown, which is as restrictive as watching a clock. We then found an electronic metronome online; using this metronome immediately standardized our pullback rates and anecdotal observation found it markedly improved our in-range LEED rates. Although pullback speeds are adjustable, we find a constant rate of 1 beat per second (60 bpm) is the most practical to use, enabling all pullbacks to be varied by seconds per centimeter. This measure is easier to practically dose than mm per second and is directly proportional to and the only determinant of LEED once power is selected. We calculate the desired pullback speed for target LEED, then corroborate and report all actual LEED delivered.

Available Options

Note: this list is not exhaustive and includes only electronic devices; we do not warranty any device and are providing information only. OsyPilot and EVLTraining must be used on the sterile field with sterile plastic cover; the others are used in either identical sterile fashion or off-field.

Electronic Devices.

The M50 Meideal metronome (Figure 1) by Shenzhen Meideal Musical Instruments Co., Ltd., Guangdong, China (<http://meideal.en.gongchang.com/product/14368256>) is powered by a CR2032 3V battery and costs less than \$10. Other features include: auditory signal, small and lightweight (56 × 31 mm; 35 g), beat structure options, programmable presets, and selectable back-beat (set at 7 seconds for ClariVein pullback). Numerous similar devices are available.



Figure 1

M50 Meideal Digital Metronome (photograph used with permission from Shenzhen Meideal Musical Instruments Co., Ltd., Guangdong, China).

OsyPilot (Figure 2) by LSO Medical, Lille, France (<http://www.osyrismedical.com/usa/equipment/osypilot.php>), costing approximately \$400, is powered by two AAA batteries, is 100 g, and has a size of 190 × 40 × 16 mm size. It is a ruler-shaped, dedicated phlebologic device; reversible visual signal of running LED lights moving at any of five fixed pullback rates (1.4–3 mm/sec, approximately 3–7 sec/cm); spatial and temporal dimensions, with the device placed next to the moving fiber.

Virtual/Computerized Devices/Applications (i.e., Apps). The SilverDial Metronome iPhone/iPad® app (Figure 3) by Foxhill Software (v.2.01; <http://silverdial.foxhillsoftware.com>) is free and ad-free (optional paid upgrade). It includes auditory and visual signals, beat structure options, programmable presets, and selectable

OsyPilot

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Figure 2

OsyPilot running LED device (photograph used with permission from LSO Medical, Lille, France).

backbeat (set meter at 7 for ClariVein). Numerous similar apps are available.

The EVLTraining iPhone app (Figure 4) by Amato Software (<http://amato.com.br/software/content/evltrainin>) costs \$5. Visual signals are included; the device is intended for practice (can be used live), with spatial and temporal dimensions, whereby the moving fiber is placed over the screen. This is a dedicated, unique phlebologic app and the only one displaying LEED, total energy, pullback rate (given as cm/sec), treatment length, and total time, all in real time and allowing corroboration of console calculations; select power, then monitor other parameters, which for the first version are continuous variables. It includes phlebology abstracts.

We find the auditory cues valuable, allowing the operator to look to and from the pullback as needed. The linear spatial cues of the OsyPilot and EVLTraining are helpful. Visual cues also are valuable in case of auditory interference from the laser tone or persons in the room. For accurate length measures, we use marked sheaths when possible; when using short unmarked sheaths, we pullback the sheath against a sterile ruler. Only the EVLTraining app measures treatment lengths. All of these devices are useful, and combinations can be helpful (an auditory metronome coupled with a

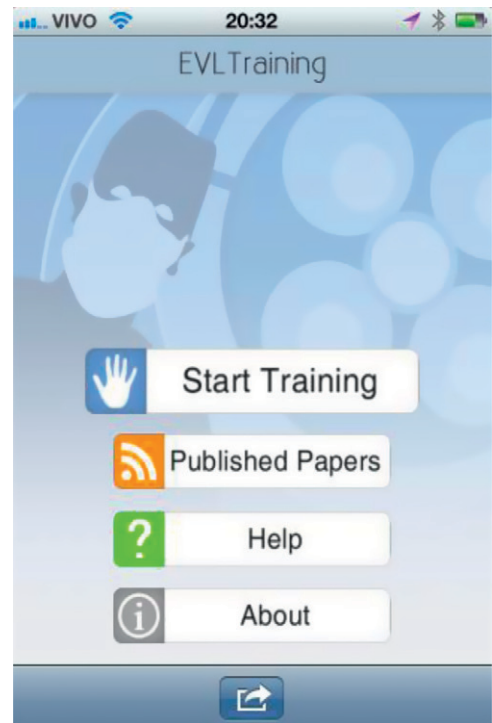


Figure 4

EVLTraining app screenshot (photograph used with permission from Amato Software).

visual cueing device). Although we have not performed formal validation studies, we have tested all, have corroborated devices against each other, and verified them against calculations performed by hand.

Conclusions

Digital or computerized metronomes and other metric devices are useful adjuncts to ultrasound-guided vein ablation procedures, the current standard of care for venous reflux disease. These cheap and facile instruments, often left to the practitioner to obtain, ensure accurate catheter/fiber pullback speed, which is the key determinant of procedural efficacy and safety and which is uniquely vulnerable to operator error in their absence.

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Figure 3

SilverDial Metronome app screenshot (photograph used by permission from Foxhill Software).