PREVENTION OF DEEP VEIN THROMBOSIS USING INTERMITTENT ELECTRICAL STIMULATION

Project SMART
Sensory Motor Adaptive Rehabilitation Technology

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Overall Goal

Explore the mechanism of action and feasibility of using intermittent electrical stimulation (IES) to prevent deep vein thrombosis (DVT).

Background

- Deep vein thrombosis (DVT) is the formation of a blood clot, often in the legs. DVT can lead to a **fatal** condition called **pulmonary embolism** (PE). PE occurs when part of the clot breaks off, travels through the blood system and forms a clot in a blood vessel in the lungs.
- DVT and PE are a leading cause of mortality and disability. There are 1.2 million cases of DVT in the United States and Canada every year. 1 out of 3 people who develop DVT will die from this condition.
- PE causes **more deaths annually** in North America **than breast cancer, AIDS and highway fatalities.**
- The cost of treating non-fatal DVT and PE (US) - $5-8 billion
- DVT can lead to **post-thrombotic syndrome,** a painful chronic condition with devastating impact on the quality of life of those affected.

Risk factors include:

Immobility, surgery, hospitalization – **75% of DVT and PE** cases are **hospital acquired,** pregnancy and postpartum, cancer, age and obesity.

http://www.webdicine.com/varicose-veins-and-deep-vein-thrombosis-what-is-the-difference.html

DVT IS PREVENTABLE

Fatal PE may be the **most common preventable cause of hospital death** in North America

Current prevention strategies:

1. *Intermittent pneumatic compression*
2. *Compression stockings*
3. *Blood thinners*

Covidien, Kendall SCD

http://en.wikipedia.org/wiki/Compression_stockings

https://drclintonb.wordpress.com/tag/premature-baby/

- Compression stockings – showed to be ineffective in preventing DVT.
- Blood thinners - increased risk of bleeding.
- Intermittent pneumatic compression – *low patient compliance*, *discomfort*, removal of inflatable cuff by patients.

Proposed intervention:

Use IES to generate contraction in the calf muscles. When muscles in the leg contract, they squeeze the leg veins, aiding in the propulsion of blood toward the heart and preventing blood stasis, one of the major initiators of blood clotting. IES will be carried out up to 24 hours/day.

Study objectives

Aim 1: Determine the level of voluntary contraction required to improve blood flow.
Aim 2: Determine IES parameters that produce the best muscle contraction for improving blood flow.
Aim 3: Test the feasibility and acceptability of the proposed treatments on inpatients in the Glenrose Rehabilitation Hospital.

Methods

Experimental design:

- To achieve aims 1 and 2 an advanced dynamometer (Biodex) will be used to measure contraction force (expressed as torque) in healthy volunteers. Doppler ultrasound will be used to measure blood flow in the popliteal vein.
- Magnetic Resonance Imaging (MRI) will be used to compare muscle deformation (change in shape) during voluntary contraction generated using IES and its effect on blood flow in the popliteal vein.

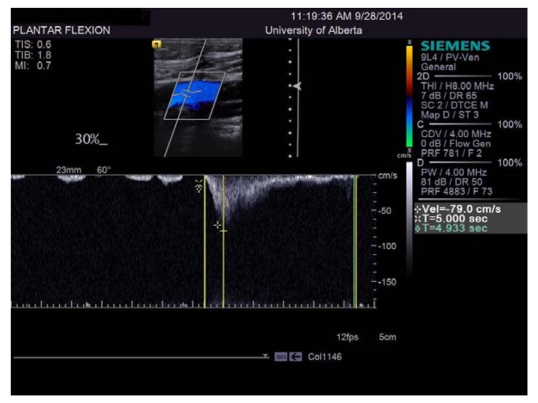
Experimental setup: The participant is seated in a recumbent position that allowed easy monitoring of blood flow with Doppler ultrasound. Force (torque) is measured during muscle contractions using a Biodex dynamometer with an ankle attachment.

- Experiment - aim 1: The participants will perform a series of contraction at increasing torques to identify the minimal voluntary contraction force required to compress the vein.
- Experiments - aim 2: IES is characterized by short "on durations (seconds) followed by long "off" durations (minutes).
  1. Determine "on" duration: Electrodes will be placed on the participant calf. Various IES "on" durations (1s to 5s) that can generate the level of contraction achieved in aim 1 will be explored.
  2. Determine "off" durations: Electrodes will be placed on the participant calf. IES will be delivered for 4 hours for each of two "off" durations (5 minutes and 7 minutes). The rate of decay in torque will be measured during this period in order to project the rate of muscle fatigue over a 24 hour period.
- Experiment – aim 3: The chosen IES parameters (aim 2) will be applied for 4 hours to calf muscle of Glenrose Rehabilitation Hospital inpatients with reduced mobility. The participants will remain in their bed. Blood flow will be monitored and the participants will provide feedback regarding the comfort level and acceptability of the stimulation.

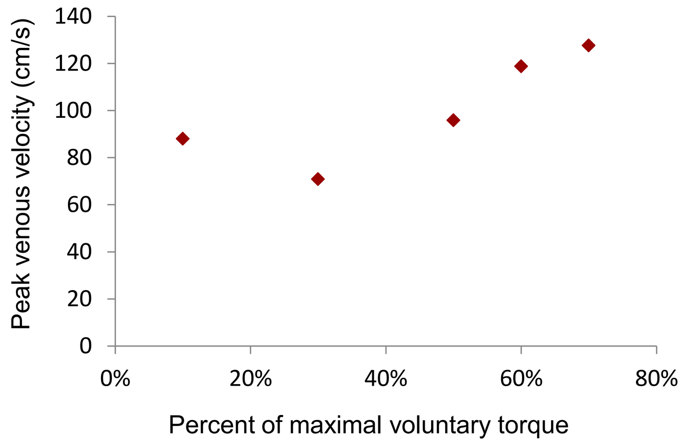
A prototype of the Smart-E-Socks : a garment with integrated electrodes designed to deliver IES to calf muscles.

Preliminary Results

Peak venous velocity was measured at the popliteal vein during various levels of voluntary contractions – male 68 y.



Measurement of peak venous velocity when the participant generated 30% of the maximal voluntary contraction.



Preliminary results indicate

- Peak venous velocity increases with increased torque.
- Complete vein compression is detected at 40%-50% of maximal voluntary contraction.

References

1. Raskob, G.E., et al., *Surveillance for deep vein thrombosis and pulmonary embolism: recommendations from a national workshop.* Am J Prev Med, 2010. **38**(4 Suppl): p. S502-9.
2. Heit, J.A., et al., *Estimated Annual Number of Incident and Recurrent, Non-Fatal and Fatal Venous Thromboembolism (VTE) Events in the US.* ASH Annual Meeting Abstracts, 2005. 106(11): p. 910-.
3. CDC, *Meeting Summary - Prevention of Hospital Acquired Venous Thromboembolism (HA-VTE) Expert Panel Meeting* 2011.
4. Ashrani, A.A. and J.A. Heit, *Incidence and cost burden of post-thrombotic syndrome.* J Thromb Thrombolysis, 2009. 28(4): p. 465-76.
6. Goldhaber, S.Z., *Venous thromboembolism: epidemiology and magnitude of the problem.* Best Pract Res Clin Haematol, 2012. **25**(3): p. 235-42.
7. Rosendaal, F.R., *Causes of Venous Thrombosis*, in *Deep Vein Thrombosis and Pulmonary Embolism*2009, John Wiley & Sons, Ltd. p. 1-26.
8. White, R.H., et al., *Incidence and time course of thromboembolic outcomes following total hip or knee arthroplasty.* Arch Intern Med, 1998. 158(14): p. 1525-31.
9. A. J. Comerota, M. L. Katz, and J. V. White, "Why does prophylaxis with external pneumatic compression for deep vein thrombosis fail?," *American journal of surgery,* vol. 164, no. 3, pp. 265-8, Sep, 1992.
10. M. Dennis, P. A. Sandercock, J. Reid, C. Graham, G. Murray, G. Venables, A. Rudd, and G. Bowler, "Effectiveness of thigh-length graduated compression stockings to reduce the risk of deep vein thrombosis after stroke (CLOTS trial 1): a multicentre, randomised controlled trial," *Lancet,* vol. 373, no. 9679, pp. 1958-65, Jun 6, 2009.
11. http://www.ohri.ca/newsroom/03152004.asp

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