**Title**

Randomised controlled trial of tourniquet associated pain generated in lower limb after exsanguination by Esmarch bandage versus leg elevation. V1.0

**Project team roles & Responsibilities**

Alexander Mitrichev, orthopaedic PHO, Townsville University Hospital, Principal investigator of trial and coordinator

John Maunder, orthopaedic PHO, Cairns Base Hospital, data analysis

Deborah Lees, orthopaedics SMO, Cairns Base Hospital, investigator of trial

Prince Singh, orthopaedic PHO, Townsville University Hospital, investigator of trial, data collection

Benjamin Parkinson, VMO Cairns Base Hospital, Investigator of trial

Research site: Townsville University Hospital, rooms in outpatient department

**Resources**

No finding required

Tourniquet machine from theatre storeroom

**Background**

Tourniquet is widely used in upper and lower limb surgeries. It stops blood flow in operative limb to allow better visualisation of surgical field and prevent blood loss during surgery. However, there are a few disadvantages to use tourniquet. The main downside is intra operative pain.

Compression form tourniquet leads to impaired metabolism in local tissues. That process disrupts CO2 and lactate clearance from muscles below tourniquet. As the result of this process acidosis and then ischemia occurs. Ischaemic type of pain was found to be less intense if adequate exsanguination of limb performed before tourniquet inflated.

Despite of theses well known mechanism no trials exist comparing methods of exsanguination in lower limbs. Indeed, the only study focusing on this clinical dilemma showed superiority of eschar tourniquet against limb elevation. Although, that trial was done on the upper limbs.

We aiming to determine which method of exsanguination will be preferrable before tourniquet is applied. The degree of patient reported pain will be the main parameter to investigate. With transcriptions of results from similar study conducted on the upper limbs we would expect that patient reported pain will be less severe in group where Esmarch is used when where the limb was simply elevated for 1 minute prior to tourniquet inflation.

**Project design**

The study will be conducted in orthopaedic clinic Cairns Base Hospital. Email with invitation will be sent to QLD health staff in Townsville University Hospital. All eligible volunteers will be randomised: one leg elevated another leg will be exsanguinated with Esmarch bandage before tourniquet is inflated on both lower limbs. We are aiming similar to previous research number of participants, at least 26. Only people fulfill to criteria’s below will be selected for study.

***Inclusion criteria***

Aged between 18 and 65 years

Good understanding of English language and able to undertake informed consent

Able to attend for study measurements

***Exclusion criteria***

Nerve problems

Diabetes, multiple sclerosis, any disease affecting sensation or function

Loss of sensation/altered sensation in the foot, leg or thigh

Weakness of leg, ankle or foot

Compressive neuropathy of lower limbs

Any type of lower limb tendinitis

Hip, knee or ankle dislocation in past 12 months

Previous trauma to hip, knee ankle or foot resulted in deficit muscles power or sensation

Thoracic, lumbar or sacral spine osteoarthritis

Previous injury, trauma or surgery on thoracic, lumbar or sacral spine

Impingement of nerves or disc herniation in thoracic, lumbar or sacral spine

Circulation problems

Sickle cell disease, Raynaud’s Syndrome or any other disease that affects circulation

Clotting problems

Any history of blood clots including deep vein thrombosis (DVT) or pulmonary embolism (PE)

High blood pressure (controlled or uncontrolled), medication for high blood pressure

Previous heart attack or stroke

Surgery or fractures within the past 12 months anywhere on the lower limbs including hips, thighs, legs, ankles or feet

Medications Warfarin, Aspirin, Clopidogrel, any other medication affecting blood clotting

Steroids, including inhalers

We will allow one week for recruitment of eligible volunteers. In this period of time all participants will have opportunity to ask question or receive more information about trial.

Consent and information leaflet will be initially attached to invitation in email. Then paper base copy of consent will be obtained on the day of investigation. Should participant choose to be not randomised this participant will be excluded from study. Any participants will have opportunity to withdraw from trial any time: before consent, during investigation or after investigation. Contact details of investigators will be included in consent form. Generic modified consent form for QLD Health portal will be employed. Alexander Mitrichev and Prince Singh will take inform consent and answer remained questions on the day of intervention. All participants will have a week to consider participation in research.

We expect to randomise and intervene on at least 4 participants (2 to each investigator) per business day and aiming to complete phase of intervention within 3 months. No formal long term follows ups are required. We will ask and record full name, age and gender of participants. Initial pain score based on visual analogue scale (VAS) will be recorded as well as blood pressure and inspection of skin. Patient will open randomisation envelope in clinic room. Once they comfortable lying down on hospital bed Esmarch bandage will be applied on one of limb depend on randomisation result. Softban Orthopaedic Wool (Smith & Nephew) will be applied to leg followed by Esmarch bandage. Another lower limb will be elevated. Researchers then will change room for blinding purposes and will inflate tourniquets on both thighs to 300mm Hg (standard pressure for lower limbs). Stryker SmartPump Dual Channel machine will be used as tourniquet (Stryker Australia Pty Ltd, ARTG entry 266269, start date 17/12/2015, no specific conditions). Swapped room researchers will record VAS score every two minutes until tourniquet is deflated and until VAS score return to baseline. Tourniquet will be deflated either when participant request it or 20 minutes after inflation whichever comes first. Main outcome will total pain score after 20 min. Secondary outcomes will be pain at every 2 minutes check, pain score after recovery phase and duration of recovery phase. Main potential adverse effects from tourniquet: pain, temporarily loss of sensation and/or changes in skin colour below tourniquet, brisk loss of muscle strength during inflation of tourniquet and early after deflation, elevation of blood pressure secondary to pain and bruises at the site of compression. Q-Q plots and Kolmogorov-Smirnov tests will be used to assess normality of outcome distribution. Paired t- tests and Wilcoxon test will be employed to analyse data from normally and non-normally distributed outcomes respectively. Fisher exact test will be the tool to analyse categorical data.

**Results, outcomes and future plans**

Copy of pain recorded sheet will be offered to each participant. All results will be recorded paper or computer with de identification. De identified data will be analysed in clinic of Cairns Base Hospital. All documents will be stored in locked drawer or hospital computers. Participants names will not be published. Once data is analysed and outcome of research is published all collected data will be destroyed.