Efficacy of Pressure Pad vs Pressure Bandage Immobilisation for Snake Bite First Aid in Healthy Volunteers.

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NCT Number: pending

Unique Protocol ID: EMLE-280R41-2024-HOLYOAK

ERM Reference Number: 109901

Document v2 date: 19/8/2024

Plain Language Summary

Snake bite affects thousands of Australians every year, but few die as a result due to high quality first aid and timely medical care. Good first aid should be simple, standardised, use minimal or readily available equipment, and be able to be utilised effectively with no or minimal training by the rescuer. Over time the first aid methods used to manage snake bite in Australia have been questioned due to issues with efficacy, and some emerging evidence of harm from their use. There is little experimental data in the literature to support current first aid practices, and what exists suggests further research is required. This project aims to examine and compare the effectiveness of two first aid methods by tracking the movement of a mock venom through the body when each first aid method is used. This will provide important information about the suitability of current techniques used in Australia and whether a proposed simpler alternative technique is as effective. If this is demonstrated to be correct it provides a basis for modifying current snake bite first aid recommendations.

Scientific Abstract

BACKGROUND/PROBLEM:
Snake bite affects over 5 million people worldwide annually with over 130000 deaths. In Australia there are over 10000 snake bites annually, with over one third of these victims being envenomated each year. Data supporting the currently endorsed method of first aid for snake bite in Australia (Pressure Bandage Immobilisation - PBI) is limited, and there is increasing evidence that the technique is often poorly applied resulting in ineffective care or even harm. A more simplistic method that is often used in countries outside Australia (Pressure Pad - PP) has more robust data supporting its use in snake bite first aid. Early and effective first aid is paramount in preventing complications of snake bite and increasing time to allow administration of antivenom and as such the most simplistic yet effective method of first aid available is advantageous.

AIMS/OBJECTIVES:
1. Determine whether the PBI technique is effective in arresting movement of a mock venom in healthy subjects
2. Determine whether the PP technique is effective in arresting movement of a mock venom in healthy subjects
3. Assess whether the PP technique is at least as effective as the PBI technique in arresting movement of a mock venom in healthy subjects

HYPOTHESIS:
The PP technique is at least as effective as the PBI technique in arresting movement of a mock venom and can be effectively applied with simple and readily available equipment.

RESEARCH DESIGN/METHODS:
Technetium-99m (Tc-99m) sulfur colloid will be used as a mock venom and injected into hands and feet of healthy volunteers after which either PBI or PP first aid

techniques will be applied. Serial images will be taken with a gamma camera to observe the passage of the mock venom through the lymphatic system. 24 healthy volunteers will be studied with repeated scans assessing the efficacy of each first aid technique on both the upper and lower limb. Time taken for mock venom to travel to regional lymph nodes and to enter systemic circulation will be measured with the first aid method in place and then following its removal.

RESULTS/ANALYSIS:
Time taken for mock venom to reach regional lymph nodes and systemic circulation will be compared between control (no bandaging/pad applied, only splinting) and each first aid method (both with first aid in situ and following its removal). This will be used to demonstrate efficacy of each technique and comparisons made between techniques.

CONCLUSIONS EXPECTED:
It is expected that both first aid techniques will be effective and will demonstrate restriction of mock venom flow while in place, and movement of mock venom following their removal. It is expected that the PP technique will be at least as effective as the PBI technique and therefore more suitable due to its simplicity of application.

Background and Rationale

Snake bite affects over 5 million people worldwide each year, with between 80000 and 137000 deaths.(1-4) In Australia there are over 10000 snake bites annually, with over one third of these resulting in envenomation.(2,5-7) Of those envenomed, only 2 to 4 die each year since the development of antivenom and the institution of appropriate first aid.(2,5,6,8)

The current standard of first aid for snake bite in Australia is the application of the Pressure Bandage Immobilisation (PBI) technique that was originally described by Sutherland et al. in 1979.(9-12) However, since the development of this technique there has been critique and debate in the medical literature surrounding the actual efficacy of the method when applied in the field.(1,2,9-11,13) Much of this critique centred around inappropriate application of the technique, insufficient pressure in the application of the bandage, or lack of immobilisation.(1,2,9,10,14,15) Despite the popularity of PBI technique, there are still large numbers of patients presenting with snake bite without having any first aid applied at all.(10,11) Retrospective analysis by some of the original publication by Sutherland has also called into question the validity of the technique itself.(9-11) Yet, with the inception of PBI and antivenom, the number of snake bite deaths in this country has decreased significantly.(2,7) As such the technique has been promulgated without much question and remains the recommended method of snake bite first aid in Australia by the Australian Resuscitation Council (ARC).(2,9-11,16) Recently however, there have been calls for more robust research into snake bite first aid, especially with growing evidence of harm (including ineffective compression, pressure injury, nerve injury, limb amputation etc) that is likely the direct result of incorrect application of the PBI technique.(1,2,9-11,17,18)

The key principles of first aid are to preserve life, prevent deterioration and promote recovery. One of the key objectives of the ARC is to promote simplicity and uniformity in techniques used for resuscitation.(19)

Australian venomous snakes of medical significance all come from the family Elapidae, which are not known for a strong localised tissue effect from their venom.(11) This is in contrast to other countries who also have venomous snakes from the Viperidae family whose venoms often contain strongly myotoxic and locally necrotic venom components.(11,20,21) As such, the PBI technique has largely been avoided in locations outside Australia due to concerns for compartmentalisation of necrotoxic and myotoxic venom worsening localised effects.(1,2,9,10,14) Promising data has emerged from research in Myanmar that supports the use of a more localised Pressure Pad (PP) or “Monash method” technique (which is popular in many areas outside Australia) that is simpler to apply correctly, less likely to cause injury to the patient, and as such may be superior to the current PBI method for Australian snake bite first aid.(1,9,10,13,14,20-23) Most notably for the PP technique, data from its use in envenomated patients does not indicate an increase in local tissue effects, even in venoms containing high proportions of myotoxic and necrotoxic components.(20,21) A further advantage of the PP technique is that can be applied to bites on the torso or abdomen, which is not the case for the PBI technique.(14)

The underlying mechanism of PBI as proposed by Sutherland is that the bandage be applied at such a pressure as to arrest flow within the lymphatic system (in most Australian snake bites, venom is injected subcutaneously and transported through the body in the lymphatic system) allowing more time for the victim to receive medical attention and antivenom when indicated.(2,7,11,12,14,24) There is reasonable consensus in published research that the required pressure to retard lymphatic flow is between approximately 50-70mmHg.(2,7,9,14) Such pressure can be delivered in the PBI technique using elasticised bandages wrapped over the entire length of the affected limb, the limb then being immobilised with a splint.(2,7,24) The PP technique as published may create a higher pressure at the site of the pad, but is only applied locally, rather than to the whole limb, again with splinting to facilitate immobilisation.(13,20-22) Importantly, for both methods, immobilisation of the limb along with the specific bandaging technique is necessary to affect a slowing of the travel of venom.(7,9-14,20-22,24) This project seeks to examine the efficacy of both the PBI and PP techniques and determine whether there is any difference between the PP technique and the PBI method as first aid, especially when using a regulated pressure of approximately 60mmHg.

Should the data from this project demonstrate the efficacy of the PP technique, given its relative simplicity, less likelihood of causing deleterious effects to the patient, and uniformity with first aid techniques used elsewhere in the world, it would give reason for the ARC to re-consider its recommended first aid treatment in Australia. An easy to use technique would also likely result in more victims of snake bite having appropriate first aid applied which may again reduce the progression of envenomation symptoms that if untreated require longer hospital length of stay.(1) Also, preventing harm from incorrectly applied first aid techniques is important in reducing morbidity associated with snake bite.

Research Aims and Objectives

1. Determine whether the Pressure Bandage Immobilisation technique is effective in arresting movement of a mock venom in healthy subjects
2. Determine whether the Pressure Pad technique is effective in arresting movement of a mock venom in healthy subjects
3. Assess whether the Pressure Pad technique is at least as effective as the Pressure Bandage Immobilisation technique in arresting movement of a mock venom in healthy subjects

Research Design and Methods

The proposed project will utilise nuclear medicine imaging to record the passage of a mock venom through the lymphatic system of healthy volunteers.

IMAGING TECHNIQUE AND MOCK VENOM CHOICE:
Technitium-99m (Tc-99m) sulfur colloid with a molecular size of 15-100nm has been chosen for use as the particles are ideal for almost isolated transport within the lymphatic system.(7) Other studies using mock venoms have used radio-labelled iodine (an even smaller molecule), and while this generated some contention as to the ability to infer movement of a large molecular weight complex protein (such as those contained in snake venoms), there has been no difference found in transit characteristics when a radio-labelled insulin was used instead.(13,22,23) Given Tc-99m sulfur colloid is readily available and its pharmacokinetics are well known, as well as being familiar to both nuclear medicine technologists and physicians in lymphoscintigraphy, it was chosen for use in this project. A standard dose for a lymphoscintigraphic study will be utilised, being 0.2mL of Tc-99m sulfur colloid (equating to 12MBq per dose) injected subcutaneously at the relevant site and first aid technique applied as outlined below. Due to the half-life of Tc-99 sulfur colloid being approximately 6 hours, serial scans on the same test subjects would be separated by at least 7 days to ensure total clearance of Tc-99m sulfur colloid prior to the next dose to avoid any potential cross contamination of imaging results. Images will be taken with a gamma camera following injection of Tc-99m sulfur colloid at 2 second intervals (and then compounded into 10 second frames for analysis).

The risks of the mock venom (Tc-99m sulfur colloid) are very low for the participants. As Tc-99m sulfur colloid is a foreign substance to the body (like any medication or treatment) there is always the possibility of allergic reaction – in this case this is very low, with the product information specifying that there are no known adverse reactions to Tc-99m sulfur colloid. Provisions are made for this rare eventuality however, with full resuscitation equipment and medications for treating allergic reactions available at the imaging facility, along with the presence of medical personnel trained in resuscitation to manage any adverse reactions or events. The risk of the additional radiation dose administered to the participants is also minimal. Normal background radiation is on average equivalent to approximately 35 chest X-

rays (2 mSv) annually in Australia. The amount of radiation exposure in this project (over the total 6 scans) is equivalent to approximately 10 chest X-rays (0.6 mSv).

Pregnancy is not a contraindication for individuals who receive Tc-99m sulfur colloid, as it has a short half-life and as such only a small radiation dose exposure, which has not been demonstrated to affect the foetus, including in the early stages of pregnancy.(25,26,27) As this project is not for direct diagnostic or therapeutic purposes that benefit the participants, it is optimal that pregnant individuals be excluded from participation. However, should a participant become pregnant during the project, the literature supports that the risk to the pregnancy and foetus are minimal.(25,26,27) As such, should a pregnancy be detected either on screening before each scan by the research team, or independently by the individual, no action other than withdrawal from the project is required. Breast feeding following receiving Tc-99m is recommended to be withheld for between 4 to 60 hours post dose,(27) but for the purposes of this project, individuals who are breast feeding are not eligible for inclusion as participants.

SUBJECT RECRUITMENT:
Healthy volunteers will be recruited through advertisement via posters distributed around the community. Volunteers who participate in the project will be supplied with a $100 gift voucher in recognition of their time commitment to the project. Other than mild discomfort from the injections and the time involved in the project there is minimal inconvenience to the participants, as parking at the radiology facility is free and readily available and travel to and from the facility should be minimal given participants will be recruited from the same general location. Given the heterogeneity of the population overall who may suffer snake bite and envenomation, screening of volunteer suitability requires the following to allow the results obtained to be generalisable to the broadest population, but also without a risk of known comorbidities that may impact on lymphatic flow biassing the results:

1. No known or clinically evident lymphatic condition (eg. lymphoedema, lymph node surgery etc)
2. No known cardiac failure
3. No known peripheral vascular disease
4. No known renal or hepatic impairment
5. No known lymphoma
6. No known allergy to Tc-99m sulfur colloid

Subjects will also be chosen based on their ability to commit to presenting for repeated scanning over the testing period to prevent loss to follow up or incomplete data. Subjects will also be requested to wear short sleeved shirts and short pants to minimise bandaging requirement over clothing. Women of childbearing potential will need to be screened for pregnancy prior to each scan, which will be undertaken on the day of each proposed scan. Withdrawal of any participant from the project at any time may be facilitated by either verbal withdrawal of consent, but ideally through signing of a written withdrawal of consent form which additionally outlines the participant’s wishes for how data already acquired through their participation in the project may be used.

For a standard two-period, two-sequence cross-over design, the investigators anticipate a sample size of N=24 will achieve 91% power at a 5% significance level

assuming the absolute difference between the two-treatment means is 1 minute and the within-subject standard deviation is 1 minute.

INCLUSION AND EXCLUSION CRITERIA:
To be included in the project, participants should:

1. Have no known or clinically evident lymphatic condition (eg. lymphoedema, lymph node surgery etc)
2. Have no known cardiac failure
3. Have no known peripheral vascular disease
4. Have no known renal or hepatic impairment
5. Have no known lymphoma
6. Have no known allergy to Tc-99m sulfur colloid

Participants will be excluded from the project if they:

1. Are under the age of 18
2. Are unable to provide written informed consent
3. Are unable to lie flat on their back for the duration of each scan (approximately 1 hour)
4. Are unable to lie reasonably still for the duration of each scan (approximately 1 hour)
5. Are pregnant or breastfeeding

TREATMENT:
Two first aid treatments for snake bite will be examined, and applied as following:

1. Pressure Bandage Immobilisation Technique (PBI):
    a. An elastic bandage of 100mm width will be applied to the full length of the involved limb, starting from the fingers or toes and moving proximally until the whole limb is bandaged, bandaging over clothing if required.(16)
    b. The desired pressure of the bandage (~60mmHg) will be obtained by utilising “smart” bandages which have special markings that take on the shape of a square when the bandage is applied at this pressure/tension. Prior to use on each subject, the accuracy of this process will be confirmed via pressure manometry using an infant blood pressure cuff bladder placed under the wraps of the elastic bandage and connected to a manometer as per Canale et al.(9)
    c. Splinting of the limb will be performed using a sling for the arm, and a wooden splint for the leg.(16)
2. Pressure Pad Technique (PP):
    a. A square gauze pad of 5 sheets thickness with an overall size of 80x80mm will be applied to the injection site.
    b. The gauze pad will be secured using an elastic bandage of 100mm width at a tension of ~60mmHg using a “smart” bandage. Prior to use on each subject, the accuracy of this process will be confirmed via pressure manometry using an infant blood pressure cuff bladder placed under the wraps of the elastic bandage and connected to a manometer as per Canale et al.(9)
    c. Splinting of the limb will be performed using a sling for the arm, and a wooden splint for the leg.
3. Control (no bandaging/pad technique applied – splint only):

a. Imaging will be done with the subject lying supine and still without the application of either bandaging technique
b. Splinting of the limb will be performed using a sling for the arm, and a wooden splint for the leg.

Injection of mock venom will be undertaken on the dorsum of the foot or hand and will comprise 0.2mL of Tc-99m sulfur colloid into the subcutaneous space. First aid techniques (including bandaging and splinting) will be applied as rapidly as possible within the first minute immediately following injection of mock venom, as has been done in previous studies.(7,13,22) Imaging with the gamma camera will begin from the time of completion of the application of first aid.

IMAGING AND DATA COLLECTION:
The following scans will be undertaken on each subject. All control scans will be undertaken for all subjects before any treatment scans are undertaken in case there are any underlying abnormalities of lymphatic flow observed which may bias results. If this is discovered, no further testing will be undertaken for that subject, and another person recruited in their place. Subjects will be randomised in a simple 1:1 ratio fashion into either one of two sequence groups: PBI first and PP second or PP first and PBI second, and again with upper limb first and lower limb second or vice versa.

	Site	**Treatment**
Scan 1	Leg	Control, splint only
Scan 2	Arm	Control, splint only
Scan 3-6 Randomised	Leg	Pressure bandage immobilisation
	Arm	Pressure bandage immobilisation
	Leg	Pressure pad
	Arm	Pressure pad

Repeated scans using the same limbs on the same subjects allows each subject to act as their own control for inherent person to person differences in lymphatic flow, and performing the scans in a randomised sequence minimises any potential bias or alteration in results due to previous testing. Testing both techniques on both upper and lower limbs will allow detection of any differences between techniques across different locations. Control scans will be conducted using splinting only to allow demonstration that any difference in lymphatic flow is due purely to the first aid technique applied (either PBI or PP).

Time (in seconds) will be recorded from the injection of Tc-99m sulfur colloid until signal is detected at the regional lymph nodes for the relevant limb, and then until there is evidence of entry to the systemic circulation (as demonstrated by signal detection in the liver). Times will be judged by the reporting radiologist based on the time stamp on the relevant image relating to signal detection at the relevant location. Each scan will run for up to 30 minutes, with intervention scans having the first aid technique removed at this point and running for a further 30 minutes. This allows demonstration of movement of mock venom through the lymphatic system after removal of first aid if the initial application of first aid is efficacious enough to

completely retard mock venom movement (thus further demonstrating the efficacy of each technique).

Distance from injection site to either groin or axilla (as relevant) will also be measured at each scan so that a lymphatic flow rate is able to be calculated.

Pressure recorded beneath the pressure bandage (as measured by manometry, described briefly above and in detail in Canale et al.(9)) will be recorded in the data spreadsheet for each patient. This measurement will be taken at the time of each control scan to ratify the function of the “smart” bandage – that being to apply a pressure of approximately 60mmHg to the limb. After taking this measurement the bandage will be removed prior to the commencement of the control injection and scan.

All imaging will be undertaken at Queensland Xray in Townsville, as there is the ability to provide uninterrupted access times to a gamma camera due to redundancy at that location.

DATA ANALYSIS:
The data obtained from this project is likely to be normally distributed and as such parametric tests will be utilised to demonstrate statistically significant differences between:

1. The time of travel of mock venom to the regional lymph nodes and to systemic circulation for each first aid treatment and control (no bandage/pad)
2. The time of travel of mock venom to the regional lymph nodes and to systemic circulation for each first aid treatment compared to the other (PBI vs PP)

Data analysis will be undertaken by the research team which includes a biostatistician. For a standard two-period, two-sequence cross-over design, the investigators anticipate a sample size of N=24 will achieve 91% power at a 5% significance level assuming the absolute difference between the two-treatment means is 1 minute and the within-subject standard deviation is 1 minute. This will allow detection of significant differences between all interventional scans and controls and determine the efficacy of each first aid technique. A >90% power has been chosen due to the paucity of data in the literature to guide better prediction of effect size.

DATA MANAGEMENT:
Project data will be recorded in a project spreadsheet which will be password protected and stored on a dedicated project USB drive, with secondary back up copies. All data stored will be deidentified and not be able to be linked back to specific participants. All data will be analysed in its deidentified form, and presentation of data will also be deidentified.

Project data will be stored for a minimum period of 15 years at which time it will be destroyed. All data will only be utilised for the purposes of this project, or future related works undertaken by the project investigators, as outlined in the patient consent form.

Raw imaging data relating to the nuclear medicine imaging will be stored using deidentified coding (so that there is no patient specific information stored on the imaging system) and is retained on the Picture Archiving and Communication System (PACS) system for the duration of the project to facilitate analysis by the research team. Upon completion of the project, this raw imaging data will be deleted permanently from the PACS system and stored only on the project USB drive for the minimum period of 15 years as above.

Innovation and Impact

Using a novel method to examine the passage of mock venom through the lymphatic system to demonstrate and compare the efficacy of two methods of snake bite first aid will provide important data that will impact the recommended first aid method for snake bite in Australia. Using a pragmatic approach to the application of the two methods provides data that best reflects what may happen in the management of snake bite victims and as such is immediately applicable to the treatment currently provided.

The impact of the findings has the potential to do the following:

1. Provide scientifically robust data to support the use of first aid treatment in snake bite by demonstrating its efficacy in retarding the movement of venom from the bite site, increasing the time for definitive treatment to occur
2. Demonstrate the efficacy of the Pressure Bandage Immobilisation technique for snake bite first aid and thus reinforce its suitability as a technique for use in Australia
3. Demonstrate the efficacy of the Pressure Pad technique for snake bite first aid which will support its existing use in countries outside of Australia, and demonstrate its potential for adoption in Australian snake bite first aid
4. Demonstrate whether there is a difference between techniques in arresting the travel of mock venom through the lymphatic system, potentially adding weight to any support for that particular method being the sole method of first aid recommended for snake bite first aid in Australia

Potential Knowledge Translation Plan/Strategy

The knowledge gained from the data generated by this project would be immediately applicable to the use of specific first aid treatments for snake bite in Australia. It would also be generalisable to other parts of the world should the Pressure Pad technique (currently used in countries outside Australia) be shown to be at least as effective as the Pressure Bandage Immobilisation technique. This information would be publicised in relevant peer reviewed journals both with a toxinology focus but also to the broader medical group as first aid treatments are relevant to a wider audience, particularly general practitioners and emergency medicine specialists. Findings from the project would also be presented at relevant conferences with a national and international focus. Submissions would also be made to the ARC to consider the

evidence currently utilised for its current recommendations for snake bite first aid and make appropriate future recommendations depending on the findings of the project.

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Budget

Budget Item	Unit Cost (AU$)	Number of Units	Budget Item Total (AU$)
Nuclear Medicine Scan	$545.90	144	$78,609.60
Research Assistant (NG7)	$70.47	144 hours	$10,147.68
Research Assistant On-costs (29.85%)	$21.04	144 hours	$3,029.76
Pressure Bandages	$20.00	96	$1,920.00
Gauze Pads (Box of 100)	$50.00	1	$50.00
Gift Cards	$100.00	24	$2,400.00
Total			**$96,157.04**

Budget Justification

PERSONNEL: A research nurse will be required to provide standardised first aid treatment application. Gift cards will be provided in appreciation for the time given by the participants in the project (up to 6 hours per participant is a significant time contribution).

CONSUMABLES & MAINTENANCE: Consumables include the bandages and pressure pad (gauze) required to administer the treatments being tested.

SERVICES: Radiology services provide the nuclear medicine scans to track the progress of the mock venom when the various first aid treatments are applied. Cost per scan is $545.90, with an aim for 24 participants total, each receiving 6x scans = 24 x 6 x $545.90 = $78,609.60 total. This includes the cost of the imaging, consumables related to the imaging, and any additional Queensland X-Ray staff time required to undertake each scan.