

Protocol

Title: A cluster randomized controlled trial of educational intervention on management of snake bite in the North Western province of Sri Lanka

Introduction

Snake bite is considered to be one of the world's neglected tropical diseases. In Sri Lanka, approximately 33,000 cases snake bites are reported annually and most of the envenoming results from the land snakes such as Russell's viper (*Daboia russelii*), hump-nosed pit viper (*Hypnale speceis*), common krait (*Bungarus caeruleus*), saw-scaled viper (*Echis carinatus*) and cobra (*Naja naja*).^{1,2,3} Being a tropical island with great diversity in geography, climate and vegetation, Sri Lanka provides the best habitat for the snakes and particularly its dry zone reports the highest incidence of snakebite with a distinctive epidemiology. Snake bite is a challenging problem for the dry zone farmer and the resulting morbidity and mortality has an impact on the economy of the country. A few decades ago victims of snake bite sought native treatment, however, currently the trend has changed and more and more patients came to government hospitals for treatment. This shift has resulted reduction of overall deaths due to snake bites, but it is rather sad to see deaths still occurring in the hospital due to avoidable reasons. It is true that, Sri Lanka lacks good antivenom which has hindered ideal management of snake bite, but modifiable factors do exist such as lack of resuscitation facilities, intensive care facilities, management guidelines, knowledge of health workers and interest of the health authorities. Local and international researchers have done adequate number of studies to describe epidemiology, clinical manifestations and management issues of snake bite in Sri Lanka. At the same time, Sri Lanka Medical Association has a dedicated committee on snake bite which provides hotline service, management guidelines and it liaise with the health authorities to show the importance of the problem. Achieving near zero death rate should be the target by improving management of snake bite in the hospital. To some extent this can be achieved by improving the knowledge of the stakeholders caring snake bite patients and changing their attitude towards these patients in the government hospitals. Thus, educational intervention has a place with aims to improve the knowledge of first contact health workers of victims of snake bite. However, systematic educational intervention had not been tested in this field and it is a novel concept. Educational intervention has no direct involvement with the patients, but we hope it will benefit patient population indirectly.

1. Alirol E, Sharma SK, Bawaskar HS, Kuch U, Chappuis F. Snake bite in South Asia: A review. *PloS Negl Trop Dis* 2010;4(1): e603.doi:10.1371/journal.pntd.0000603
2. Kasturiratne A, Pathmeswaran A, Fonseka MM, Lalloo DG, de Silva HJ. Estimates of disease burden due to land-snakebite in Sri Lankan hospitals. *Southeast Asian J Trop Med Public Health* 2005;36:733–40.
3. Kularatne SAM, Clinical profile of snake envenoming: A study in North Central Province of Sri Lanka. The 23rd Bibile Memorial Oration in 2001. *SJM* 2001;10:4–12.

Hypothesis: Systematic educational program to improve the knowledge of the first contact doctors and nurses in the management of snake bite will reduce the snake bite related morbidity, mortality and direct costs involved in the government hospital in Sri Lanka

Objectives

To introduce an educational intervention program based on Sri Lankan national treatment guidelines to improve the outcomes (morbidity, mortality, standards of management) and cost involved in snake bites.

Method

The educational intervention will follow the randomization of institutions into two arms;

Group A- Full intervention (SLMA guidelines, Poster, Training & BHT folios)

Group B- Control group

Type of intervention

1. Documentation (user friendly, preformatted comprehensive annexures to the admission form (BHT folios) of snake bite patients). Introduction of additional educational charts with important messages: e.g. treatment of anaphylaxis.
2. Workshops to educate the first contact doctors & nurses representing all the hospitals of the intervention area
3. Distribution of educational materials: a poster depicting pictures of deadly venomous snakes and essential management steps in an algorithm. This will be supported by promotional items such as pens with messages to use the snake assessment and treatment protocol
4. Identifying the availability and deficiencies of essential drugs and materials in the resuscitation trolley in each hospital and to take remediable actions in case of deficiencies: Ambu bags and test tubes for WBCT 20 etc.

Timing of Intervention

Monitoring of the 1st phase of the intervention will last 6 months (May 2013 to November 2013) .

2nd phase of the intervention will start immediately when Group B will be given the full intervention. Monitoring the phase will continue for 6 months (December 2013 to May 2014).

At the end of one year the study will be over.

Study area

In Kurunegala District of North Western Province (NWP) of Sri Lanka that includes 44 hospitals except teaching hospital Kurunegala. However, monitoring will be done at TH Kurunegala to verify transfers.

Sample Size

In 12 months 2010-2011 approximately 4700 patients were admitted to Kurunegala District primary hospitals. This study will look at pre and post intervention changes in individual hospitals documentation and stocking of resuscitation trolley.

Study collaboration

Provincial Director of Health NWP

Randomization: Cluster randomization was done by an independent statistician. Following variables were used- category of hospitals (Base, District, Peripheral), Number of snakebite admission and geographical areas of the hospital in relation to Kurunegala district. Finally 24 hospitals came under one group and 20 hospitals came under one group. Using a toss these two groups were selected for test and control group

Details of Educational workshop

- Venue - NWP
- Date - 15th May 2013 (2nd stage – proper intervention)
- Participants - 1 Doctor & 1 Nurse
- Administrative Support – PD & RD

Workshop (in two sessions)

A full day interactive teaching session: Training in management of snake bite and allergic reactions to antivenom.

Target group

Medical officers working in primary health care institutions
(Pre-intervention knowledge of participants will be assessed by simple pre-intervention test)

Objectives to achieve after the workshop

To improve the ability to identify the offending snakes

To improve the ability to detect evidence of envenoming

Detection of complication and deciding on appropriate referral

Implementation of lifesaving steps during referrals

Appropriate use of antivenom

Correct management of antivenom reactions

Training the participants to be trainers in their respective hospitals

Assessments

- First assessment will be done at the training work shop
- Second assessment will be done at the end of 6 months
- Third assessment after one year

Assessments tools

- **Pre and Post test** – at the workshop
- **Improvement of documentation** – after 6 months & 12 months
20 pre-determined points in the BHT folios will be tested
- **Improvement of Management** - after 6 months & 12 months
Outcome, number of transfers and a grading by an expert on management (Grade 1 – Excellent, Grade 2 – Good, Grade 3 – Poor). For that all BHTs will be scanned with the permission of the PDHS, North Western Province. These documents will be treated as confidential and access will be available only for the chief investigator.

Assessment of outcome

Primary Outcomes

- Assessment of documentation
- Percentage of appropriate and inappropriate referrals or transfers
- Percentage of patients managed at primary care level and sent home (non venomous bites, dry bites and venomous bites)
- Delays at door to needle time, transfers
- Audit of correct management steps of anaphylactic reactions (No of cases)
- Maintenance of resuscitation trolley
- Stocking of antivenom and appropriate antivenom use (number of patients, number of vials)
- Testing the knowledge with questionnaire (post intervention)
- Focus groups will be conducted with staff for feedback regarding the intervention
- Analysis of the Auditing key
- Direct costs will be calculated by using preset rules for appropriate use of antivenom and transfer

Secondary Outcomes

- Mortality at different levels
- Audit of morbidity of transferred cases at referral hospitals

Ethical Issues

This study will use information extracted from the BHT into a study database. The patient information will be de-identified.

Potential benefits of the project.

1. Understanding and documenting accurate epidemiology of snake bite in the NWP
2. Identifying deficiencies that are remediable to improve the management of snake bite in NWP. e.g. knowledge, skills, documentation, materials, infrastructure, antivenom stocking and distribution.
3. Training trainers for continuation of education on management of snake bite and to maintain enthusiasm.
4. Improvement of outcomes of envenoming and building trust of public on hospital treatment. This will draw people coming to hospital immediately after snake bite without seeking harmful alternative treatments.
5. Cost benefits for the NWP and the government by streamlining management and limiting wastages
6. Capacity building for future research and awareness programmes in NWP
7. Help in future health planning
8. Developing NWP as the rolemodel of snake bite care and expanding to other provinces.