**Efficacy and safety of thermotherapy versus intra-lesional sodium stibogluconate in *L donovani*-induced cutaneous leishmaniasis: A randomized controlled clinical trial**

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Cutaneous leishmaniasis (CL) in Sri Lanka is caused by the dermotropic variant of *L donovani*. Routine treatment used is weekly injections of intralesional sodium stibogluconate (SSG) for several weeks, which is painful, costly and requires several hospital visits by the patient with increasing numbers of patients showing lack of or delayed treatment response, hence the need to explore alternative treatment methods. Thermotherapy has been found to be effective and safe in the treatment of CL caused by *L tropica* and *L major* in the old world, but efficacy and safety in CL caused by *L donovani* has not been established thus far.

To assess the efficacy and safety of thermotherapy in comparison to standard intra-lesional SSG in the treatment of CL caused by *L donovani*

Two hundred and thirteen patients with single parasitologically- confirmed CL lesions were randomly assigned to two groups. The test group (n=98) received a single session of topical radio-frequency induced heat therapy (RFHT) at 50ºC for 30 seconds and the control group (n=115) received intra-lesional sodium stibogluconate (IL SSG) weekly until cure or up to 10 doses. Patients were followed up fortnightly up to 12 weeks to assess clinical response and occurrence of any adverse events.

The cure rates by 8, 10 and 12 weeks in the thermotherapy group were 50%, 58.5% and 70.5% as opposed to 33.3%,52.3% and 70.5% in the IL SSG group. The cure rate by thermotherapy was significantly higher (p=0.041) at 8 weeks, while they were comparable thereafter. At 8 weeks, the response to thermotherapy was significantly better in females, younger age groups and papular lesions, when compared to those treated with IL SSG (p=0.004, p=0.029 and p=0.037 respectively). Lesion size and duration of lesion had no effect on cure rates between the groups. No major adverse events were recorded in either group.

A single application of thermotherapy was found to be safe, effective and patient-friendly as compared to multiple doses of IL SSG in the treatment of *L donovani*  CL.