

Title: Diagnosis of localized cutaneous leishmaniasis and treatment outcomes following carbon dioxide cryotherapy performed by health centre staff : a pilot implementation study in Ethiopia

Abstract

Introduction: In Ethiopia, the incidence of cutaneous leishmaniasis (CL) is estimated to range from 20, 000 to 30, 000 new cases due to *Leishmania aethiopica*. Children and young adults, in rural communities with limited access to health care are most affected. The current standard of care, pentavalent sodium stibogluconate is only administered in specialist centres, has limited effectiveness and is associated with severe adverse effects. Cryotherapy is recommended in national guidelines at the primary care level to treat uncomplicated CL , but is rarely available due to limited numbers of trained clinicians and lack of resources. We co-developed and evaluated a decentralised intervention, administered at a rural health centre, using carbon dioxide (CO₂) cryotherapy, which is available for the treatment of cervical dysplasia.

Methods and materials: A pragmatic clinical trial design was used, providing training at the health centre that combined theoretical instruction with direct patient assessment. Study clinicians recruited patients with suspected CL who had a slit-skin smear performed with confirmation by expert microscopists. The diagnostic accuracy of trained clinical and laboratory staff at a rural health centre were compared to experts. Individuals aged ≥ 12 years with parasitologically confirmed uncomplicated CL received CO₂ cryotherapy. Participants were followed until Day 90. Cure was defined as complete re-epithelialization of the index lesion.

Results: We trained seven clinicians and laboratory professionals at Keteteya Health Centre. Of 331 individuals who attended the clinic with skin disease, 158 (47.7%) were clinically diagnosed by trained clinical staff with CL. Overall 123 had laboratory confirmed CL and of these 85 (53.8%)

received CO₂ cryotherapy. By Day 90, 68 of 77 (88.3% (95% CI: 78.5–94.1%)) were cured. Adverse events were mild and transient, with no individual discontinuing treatment.

Conclusion: Trained health centre clinical and laboratory staff were able to accurately diagnose CL. CO₂ cryotherapy was safe and efficacious when administered by trained staff. A training programme to facilitate CO₂ cryotherapy appears to be a feasible approach to decentralizing CL diagnosis and treatment to primary healthcare facilities in endemic areas of Ethiopia.

Keywords: Localized cutaneous leishmaniasis, *Leishmania aethiopica*, diagnostic accuracy, carbon dioxide cryotherapy, efficacy, Ethiopia