OP-08: Improved in-house ELISA assay for serodiagnosis of *Leishmania donovani* induced cutaneous leishmaniasis in Sri Lanka

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Introduction: In Sri Lanka, cutaneous leishmaniasis (CL) is caused by a genetic variant of a visceralizing parasitic species called *Leishmania donovani*. A high seroprevalence of 82% has been observed in Sri Lanka during a previous study. The National Action Plan of Leishmaniasis Control of Sri Lanka and the World Health Organization have recognized the significance of the development of diagnostic methods in disease control. Sensitive serodiagnostic methods will minimise the cost, need for second-line investigations, and need for methods that require invasive sampling. In this study, the diagnostic accuracy of a previously developed ELISA assay was improved further.

Methods: A total of 100 samples were used (50 laboratory confirmed CL, 50 controls). Modified and previously used methods were utilised. The composition of the cell lysis buffer, blocking buffer, concentration of primary antibody and incubation periods were modified. Standard statistical methods using SPSS were used for data analysis and validation.

Results: The original method showed 78.0% sensitivity, positive predictive value of 97.5% and negative predictive value of 81.7% at a high specificity of 98.0%. The modified method showed 86.0% sensitivity, positive predictive value of 97.7% and negative predictive value of 87.5% at 98.0% specificity. The sensitivity of modified ELISA could be further increased up to 94.0% with a reduction of specificity to 86.0%. However, this was not further examined since a high specificity is also required in a tropical setting where many clinically similar conditions are prevalent.

Conclusions: Since established serological tools gave poor response locally, improving and assessing the usefulness of the tools both in patients and field asymptomatic case screening in local settings will be useful. The modified ELISA assay can be used in the laboratory for confirmation of active CL. Its ability to be used in the field screening of asymptomatic cases can also be evaluated.

Keywords: ELISA, cutaneous leishmaniasis, *Leishmania donovani*, Sri Lanka