

INFECTIOUS DISEASES (BACTERIAL, FUNGAL, VIRAL, PARASITIC, INFESTATIONS)

## **RANDOMIZED, DOUBLE BLIND STUDY ON INTRALESIONAL METRONIDAZOLE VS INTRALESIONAL SODIUM STIBOGLUCONATE IN L. DONOVANI CUTANEOUS LEISHMANIASIS**

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Background: Cutaneous leishmaniasis (CL) has become endemic in several parts of the world including Sri Lanka. Efficacy of metronidazole in cutaneous Leishmaniasis was proven by few case reports and clinical trials. Aim of our study was to assess the efficacy of intralesional metronidazole on L. donovani CL.

Material and Methods: 188 patients with CL were randomly allocated to intralesional sodium stibogluconate (SSG) and intralesional metronidazole. Cure was assessed after 1-10 injections. Cure rates were assessed for statistical significance using Chi square test at  $p = 0.05$  level. Clinical trial registry No: SLCTR/2014/028.

Results: When the treatment cut off was taken at 100%, the rate of cure for SSG ( $n=64$ , 65.6%) was higher than that of metronidazole ( $n=45$ , 48.9%): statistically significant at  $p<0.05$  level (Yates corrected Chi Square 5.37,  $df = 1$ ,  $p<0.5$ ). When the treatment cut off was taken at  $>80\%$ , the rate of cure for SSG ( $n=75$ , 77.1%) was also higher than that of metronidazole ( $n=58$ , 63.0%): statistically significant at  $p<0.05$  level (Yates corrected Chi Square 4.46,  $df = 1$ ,  $p<0.5$ ). Since it is based on a smaller sample, we estimated the statistical power of the test at a cut off of 100% [above 80%] results identified a risk ratio of 1.4 [1.3], and a statistical power based on normal approximation at 74.8% [70.0%] respectively.

Post inflammatory hyperpigmentation and pain at injection site were equal and common to both groups. Ulceration was more with sodium stibogluconate ( $n=5$ ) than with metronidazole ( $n=2$ ). Within 6 months of follow up period one patient had recurrence in Sodium stibogluconate group and two had recurrences in metronidazole group. One treated with metronidazole developed satellite lesions three months after 100% clinical cure.

Conclusion: This study showed that intralesional SSG has the best response against cutaneous leishmaniasis, while intralesional metronidazole was an effective alternative



treatment.

