Combination of sodium stibogluconate and rifampicin in post kala-azar dermal leishmaniasis

Sir,

Sodium stibogluconate (SSG) is the standard drug used for the treatment of post *kala-azar* dermal leishmaniasis (PKDL) at a dose of 20 mg/kg/day (maximum 850 mg/day) for at least 4 months. However, many patients are unable to complete the recommended duration of therapy because of the side effects such as elevated liver enzymes, proteinuria, and severe myalgia. It has been reported that up to 65% of the previously untreated patients fail to respond or promptly relapse after therapy with antimony compounds.[1,2] Treatment with other drugs such as ketoconazole, amphotericin B, and allopurinol is also not satisfactory due to their side effects and prolonged therapy. In view of the above, the development of combination regimens for the treatment of PKDL has been proposed.[3,4] We report the safety and efficacy of combination therapy with SSG 10 mg/kg/day I.V and rifampicin 900 mg daily orally for a period of 120 days in PKDL.

About eight male patients with an average age of 24.8 years (range 18-39 years) were included in this prospective hospital-based, descriptive preliminary study, which was carried out over a period of 2 years. The duration of skin lesions of PKDL ranged from 5 months to 10 years (mean 2.8 years). All the eight patients had a past history of *kala-azar* and the period of onset of PKDL after *kala-azar* varied from 6 months to 10 years (mean 2.81 years).

Hypopigmented macules and erythematous, shiny, succulent papules were present in all the patients and larger nodules were seen in four patients. The erythematous indurated lesions were present on the nose (7/8), chin (7/8), ears (6/8), external genitalia (4/8), glabella (2/8) and on the forehead, cheeks, lips (1 patient each). None of them had mucosal lesions or hepatosplenomegaly. Four of the eight patients had been treated previously with SSG at a dose of 600-1000 mg daily (two patients received for 90 days, one for 35 days and the other one for 10 days) without much response. Skin biopsy demonstrated a dermal infiltrate of lymphocytes, histiocytes, and plasma cells in all the patients. LD bodies were demonstrated in nodular lesions in four patients on tissue smears. Pulmonary tuberculosis was detected on chest X-ray in one patient.

About six patients completed the treatment as one of the patients developed leucopenia while the other was lost to follow up after 56 days. Five of them had an excellent response. The onset of the response was noted as early as 1 week and all the five patients had started responding by 3 weeks of therapy. Facial lesions healed completely in all cases by 3 months. The hypopigmented macules repigmented completely in three patients [Figure 1]. The patient who was lost to follow-up after 56 days of therapy had 90% reduction in the facial lesions and 50% reduction in genital lesions. No recurrence was noted in the five patients who had an excellent response after a mean follow up period of 12 months (range 2 to 30 months).

The side effects due to the combination therapy were seen in five patients and were minor like myalgia (4/8), thrombophlebitis (3/8), headache (1/8), arthralgia (1/8), transient leucopenia (1/8), and elevated transminases (1/8).

Our report demonstrated an excellent response in five of the

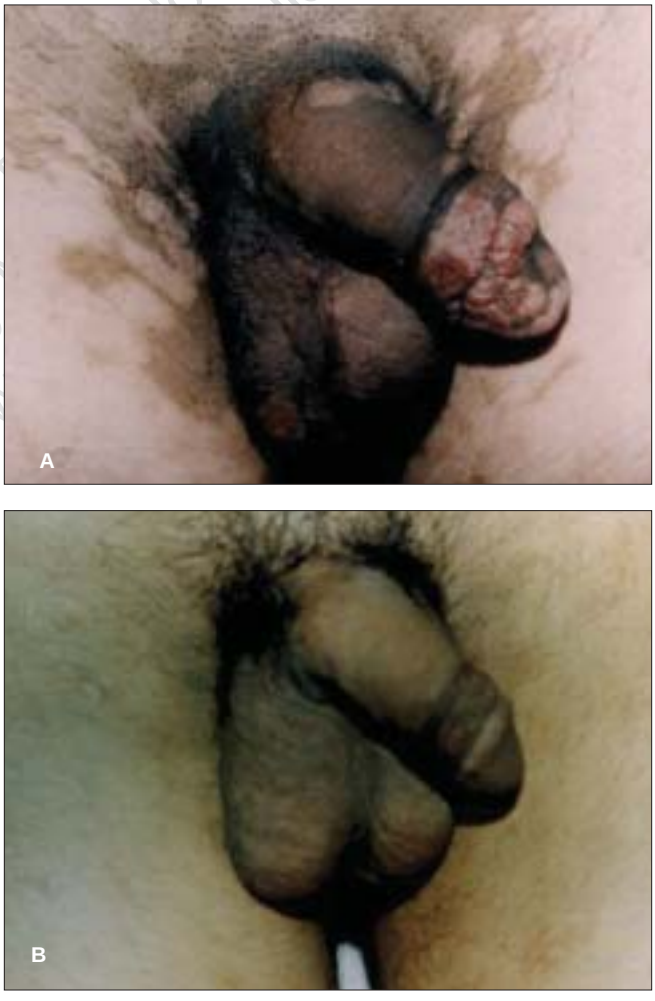

Figure 1: Resolution of the hypopigmented and papulonodular lesions. (A) Pre-treatment, (B) At 1 year post-treatment follow-up

six patients who completed the treatment schedule without any relapse during the follow-up. The compliance was also good, with only one patient being lost to follow-up, probably as a result of reduced toxicity and earlier response. This preliminary study shows that the combination of SSG and rifampicin for 120 days is effective and reasonably safe in the treatment of PKDL.

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