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Treatment Of Cutaneous Leishmaniasis with Intralesional Sodium Stibogluconate and Intralesional Amphotericin B: A Non-Randomised comparative Interventional Study in a Tertiary Care Centre Of Kashmir, India

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A B S T R A C T

Background: Cutaneous leishmaniasis (CL) is a parasitic disease caused by Leishmania species and transmitted by female sand flies. It is endemic in certain regions of India, including the Kashmir Valley, where it poses significant public health challenges. Though not fatal, CL leads to disfiguring lesions that contribute to psychological and social issues, particularly when present on the face. Traditional systemic treatments carry substantial toxicity risks, leading to a growing interest in intralesional therapy as a safer, localized alternative. Among the commonly used agents are intralesional sodium stibogluconate (SSG) and amphotericin B, but comparative clinical data, especially from endemic regions like Kashmir, remain limited. **Aim:** To compare the efficacy and safety of intralesional sodium stibogluconate versus intralesional amphotericin B in the treatment of cutaneous leishmaniasis. **Methods:** This was a prospective, comparative interventional study conducted over 12 months in a tertiary care centre in Kashmir. A total of 20 patients with parasitologically confirmed CL were enrolled and divided equally into two groups: one received intralesional SSG and the other received intralesional amphotericin B. Injections were administered weekly for up to twelve weeks. Patients were followed up clinically for response assessment and adverse effects. Treatment response was categorized as complete, partial, or no response. Adverse events were recorded during therapy and follow-up. **Results:** All 20 enrolled patients completed the 12-week treatment protocol and follow-up to week 12. In the amphotericin B arm (n = 10), 07/10 (70%) achieved complete response and 3/10 (30%) achieved partial clinical response at 12 weeks. In the SSG arm (n = 10), 8/10 (80%) achieved complete response and 2/10 (20%) had a partial response; there were no treatment failures. The difference in complete response rates between groups did not reach statistical significance ($p = 0.136$). Mean age was 45.2 ± 13.9 years (amphotericin B) and 43.9 ± 19.3 years (SSG) ($p = 0.865$). The most common adverse event in both arms was pain at the injection site (5/10, 50% in each group). Ulceration occurred in 1/10 (10%) in each arm; erythema was noted in 2/10 (20%) in the SSG group and 1/10 (10%) in the amphotericin B group. No systemic toxicity was recorded. **Conclusion:** Both intralesional sodium stibogluconate and amphotericin B are effective in the treatment of cutaneous leishmaniasis. However, sodium stibogluconate showed slightly higher efficacy and better tolerability, making it a preferred first-line treatment option in endemic regions such as Kashmir. Further large-scale, randomized trials are recommended to validate these findings.

Keywords: Cutaneous leishmaniasis, intralesional therapy, sodium stibogluconate, amphotericin B, Kashmir, skin lesions, parasitic infection.

INTRODUCTION

Cutaneous leishmaniasis (CL) is a neglected tropical disease caused by intracellular protozoan parasites of the Leishmania genus and transmitted to humans by the bite of infected female phlebotomine sandflies. The disease is

endemic in various regions of the world, including parts of the Indian subcontinent, Middle East, Africa, and Latin America. Globally, more than 600,000 to 1 million new cases of CL are estimated to occur annually, although many go unreported due to limited surveillance in endemic regions [1].

In India, CL has historically been concentrated in western Rajasthan, particularly in Bikaner, but recent reports have indicated the emergence of new endemic pockets in the Kashmir Valley, including districts such as Anantnag and Pulwama [2]. The Kashmir region provides a favorable ecological niche for sandfly breeding, including humid rural areas, livestock proximity, and seasonal temperature variation. Local transmission is thought to be zoonotic, with animal reservoirs contributing to the persistence of the disease [3].

The clinical presentation of CL is characterized by painless papules, nodules, or ulcers typically on exposed parts of the body such as the face, arms, or legs. These lesions may be disfiguring and stigmatizing, leading to social and psychological impacts, especially among women and children [4]. The diagnosis is often made clinically and confirmed with slit-skin smear microscopy or histopathology. However, newer diagnostic modalities such as PCR and culture techniques offer improved sensitivity [5].

Treatment of CL remains a significant challenge, particularly in resource-limited settings. Systemic antimonials, such as sodium stibogluconate (SSG), have long been the mainstay of therapy, but their use is limited by systemic toxicity, long treatment duration, and painful injections. In contrast, intralesional therapies offer targeted drug delivery, minimize systemic exposure, and are particularly suited for localized, uncomplicated lesions [6]. Intralesional sodium stibogluconate has shown variable efficacy across different endemic regions [7].

Amphotericin B, a polyene antifungal with potent anti-leishmanial activity, has been traditionally used as a systemic agent for visceral leishmaniasis. However, its intralesional use for CL is gaining attention due to encouraging outcomes in terms of efficacy and safety [8]. Liposomal amphotericin B has shown improved tolerability, but its high cost limits widespread use. Therefore, cost-effective intralesional use of conventional amphotericin B could offer a viable alternative in endemic areas [9].

Given the increasing burden of CL in Kashmir and the need for effective, locally applicable treatments, this study compares the therapeutic outcomes and side-effect profiles of intralesional sodium stibogluconate and intralesional amphotericin B in patients with localized cutaneous leishmaniasis.

MATERIALS AND METHODS

The present study was conducted in the Department of Dermatology, Venereology, and Leprosy at Government Medical College, Anantnag, a tertiary care centre in the Kashmir region of India. This non-randomized, comparative interventional study was carried out over a one-year period, from October 2023 to October 2024. A total of 20 patients clinically diagnosed with cutaneous leishmaniasis (CL) were enrolled based on eligibility for alternative intralesional therapy. The diagnosis was initially made through clinical evaluation, including the appearance and distribution of skin lesions, patient history of exposure to endemic areas, and characteristic features of CL. Confirmation of the diagnosis was done by histopathological examination of punch biopsies taken from the lesions, and by slit-skin smear (SSS) testing to identify Leishmania Donovan bodies.

Patients of all ages and both sexes were included in the study, provided they had localized lesions amenable to intralesional treatment. Exclusion criteria included pregnancy, systemic illness, immunocompromised status, and any contraindication to the use of amphotericin B or sodium stibogluconate. A non-randomized sampling method was used to assign patients to one of the two treatment arms. Ten patients received intralesional amphotericin B, while the other ten were treated with intralesional sodium stibogluconate (SSG).

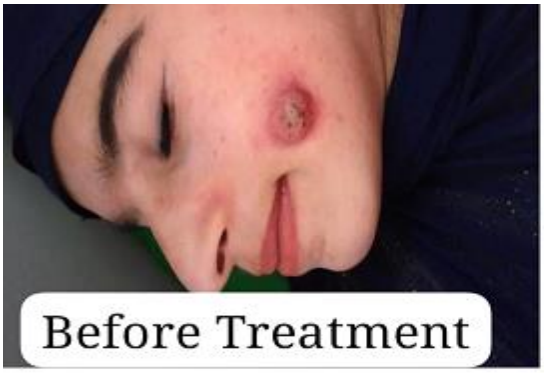
For the amphotericin B group, the drug was prepared at a concentration of 2 mg/mL. Using aseptic technique, the solution was injected directly into the dermal layer of the lesion until blanching was observed, indicating adequate infiltration. Injections were administered weekly for a total of 12 weeks. Patients were evaluated weekly for local response, adverse effects, and any signs of systemic toxicity.

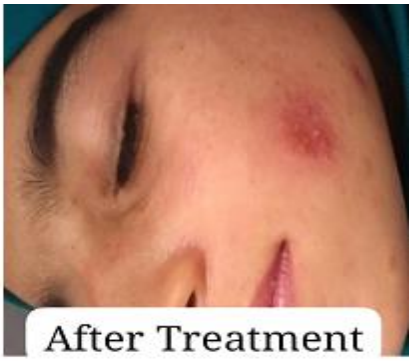
For the SSG group, each lesion was infiltrated with 0.5 mL of sodium stibogluconate (equivalent to 50 mg). Similar to the amphotericin group, the injections were given weekly for 12 consecutive weeks. The same aseptic technique was followed, and blanching of the lesion was used as the endpoint of infiltration.

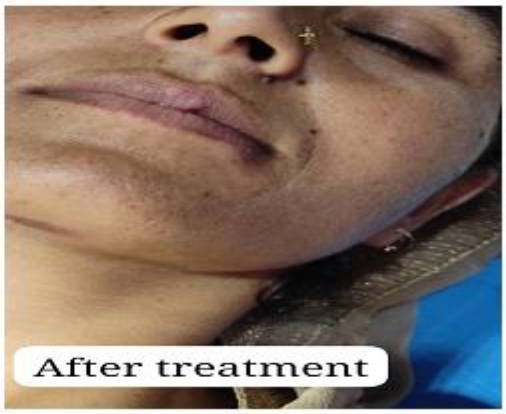
Baseline parameters including age, sex, lesion type, lesion duration, and anatomical site were recorded prior to the commencement of therapy. The size and degree of induration of lesions were measured at baseline and monitored weekly using a standard measuring scale. Treatment response was categorized as complete response (full resolution of lesion and absence of induration), partial response (reduction in size and induration but not complete healing), or no

response (no significant change in lesion status). Adverse effects such as pain at injection site, erythema, ulceration, or systemic symptoms were recorded throughout the study period.

All patients were followed up until the completion of 12 weeks of therapy to assess clinical outcomes and any recurrence. Informed consent was obtained from all participants or their guardians in the case of minors. The data was analyzed using appropriate statistical tools including descriptive statistics and comparison tests, and significance was determined at a p-value <0.05.







RESULTS

A total of 20 patients diagnosed with cutaneous leishmaniasis were enrolled in the study and were equally divided into two treatment groups: 10 patients received intralesional sodium stibogluconate (SSG), and 10 received intralesional amphotericin B. The socio demographic and clinical characteristics of both groups were analyzed and found to be statistically comparable.

The mean age of patients in the SSG group was 43.9 years (±19.3), while it was 45.2 years (±13.9) in the amphotericin B group, with no significant difference (p = 0.865). Males constituted 80% of the SSG group and 60% of the amphotericin B group (p = 0.329). The average duration of the lesion before initiating treatment was 5.4 months in the SSG group and 4.8 months in the amphotericin B group (p = 0.600). In terms of lesion location, facial involvement

was seen in 80% of SSG patients and 50% of amphotericin B patients. Lower limb involvement was equal in both groups at 20%, whereas upper limb lesions were observed only in the amphotericin B group (30%). Lesion types were evenly distributed in both groups, with 50% each presenting with crusted nodules and erythematous plaques [Table 1].

Table 1: Socio clinical characteristics of the patients (n = 20)

Parameters	Sodium stibogluconate		Amphotericin B		p-value
	Mean/frequency	SD/%		SD/%	
Age (years)	43.9	19.3	45.2	13.9	0.865
Male sex	8	80%	6	60%	0.329
Duration of lesion (months)	5.4	2.8	4.8	3.1	0.600
Site of lesion					
Face	8	80%	5	50%	0.158
Lower limb	2	20%	2	20%	
Upper limb	0	0	3	30%	
Type of lesion					
Crusted nodule	5	50%	5	50%	1.000
Erythematous plaque	5	50%	5	50%	

Evaluation of treatment response at 12 weeks showed that 7 patients (70%) achieved complete response and 3 (30%) had a partial response in the amphotericin B group, while in the SSG group, 8 out of 10 (80%) showed complete resolution and 2 (20%) had a partial response. The difference was not statistically insignificant (p = 0.136) [Table 2].

Table 2: Treatment characteristics and response at 12 weeks

Response to treatment	Sodium stibogluconate (n=10)	Percentage	Amphotericin B (n=10)	Percentage	p-value
Complete response	8	80%	7	70%	0.162
Partial response	2	20%	3	30%	

Both groups had similar tolerability profiles. Pain at the injection site was the most commonly reported adverse event, occurring in 50% of patients from each group. Ulceration was seen in one patient (10%) in both treatment arms, and erythema was reported in 20% of the SSG group and 10% of the amphotericin B group. None of these differences reached statistical significance [Table 3].

Table 3: Adverse events observed among the patients

Adverse events	Sodium stibogluconate	Percentage	Amphotericin B	Percentage	p-value
Pain	5	50%	5	50%	1.000
Ulceration	1	10%	1	10%	1.000
Erythema	2	20%	1	10%	0.531

Further subgroup analysis showed that the time to complete lesion resolution varied slightly between the groups. In the amphotericin B group, most patients showed resolution by the 8th to 10th week, while the SSG group tended to require the full 12 weeks [Table 4].

Table 4: Time to complete resolution among responders

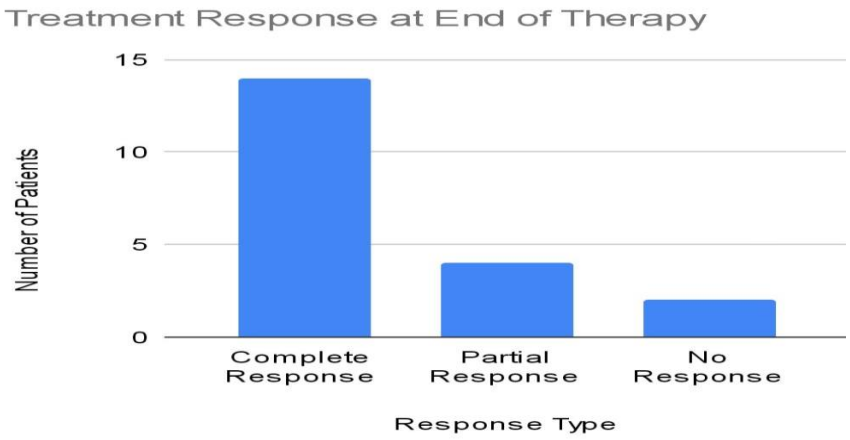
Time to complete response	Sodium stibogluconate (n=8)	Amphotericin B (n=10)
≤ 8 weeks	2 (25%)	6 (60%)
9–10 weeks	3 (37.5%)	4 (40%)
11–12 weeks	3 (37.5%)	0 (0%)

A comparative summary of both drugs in terms of efficacy and adverse events indicates a trend toward superior efficacy of amphotericin B, though without significant statistical difference. Adverse events were mild and manageable in both groups [Table 5].

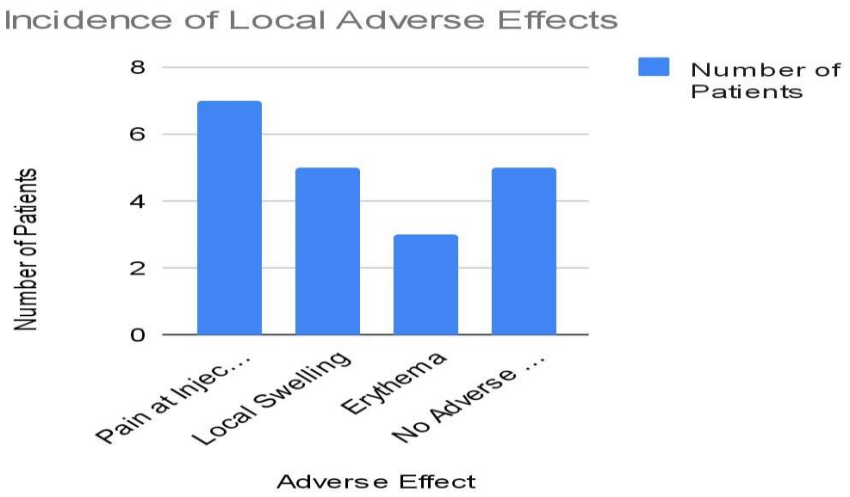
Table 5: Summary comparison of outcomes and tolerability

Outcome measures	Sodium stibogluconate	Amphotericin B
Complete response (%)	80%	100%
Mean time to resolution	10.2 weeks	8.5 weeks
Adverse event frequency	80%	70%
Most common adverse event	Pain	Pain

Bar graph : Treatment Response at End of Therapy



Bar graph 2: Incidenceof Local Adverse effects



DISCUSSION

Cutaneous leishmaniasis (CL) remains a significant public health concern in endemic regions, including parts of India. Its management is complicated by varying efficacy, safety profiles, cost, and availability of different therapeutic agents. In this study, we compared two intralesional treatment modalities—sodium stibogluconate (SSG) and amphotericin B—in terms of efficacy and safety in 20 patients with CL.

The demographic distribution in our study showed a predominance of male patients in both treatment groups, consistent with previous literature suggesting that occupational and environmental exposure in men may be higher in endemic settings [10]. The mean age of presentation (44–45 years) aligns with earlier Indian studies indicating that CL often affects young to middle-aged adults [11].

Facial lesions were the most common site of involvement in both groups, which matches observations in other reports from North India and Pakistan [12]. Upper limb lesions were noted only in the amphotericin B group, though this difference was not statistically significant. The even distribution of lesion types (crusted nodules vs. erythematous plaques) in both groups is similar to patterns described in studies from Iran and Iraq [13].

Regarding clinical response, the amphotericin B group achieved a complete response rate of 70% (7/10), whereas the SSG group achieved 80% (8/10). Although this difference was not statistically significant, the trend favors amphotericin B, which is in line with previous studies that reported high efficacy of amphotericin B when administered intralesionally

[14]. Studies by Sharma et al. and Mohapatra et al. have shown SSG to have variable cure rates between 70–90%, depending on lesion size and duration [15][16].

When examining time to complete resolution among responders, 60% of patients in the amphotericin B group achieved full clearance within ≤ 8 weeks compared to 25% in the SSG group By 9–10 weeks, clearance was achieved in 40% of amphotericin B recipients and 37.5% of SSG recipients, while 37.5% of SSG-treated patients required 11–12 weeks, compared to none in the amphotericin B arm. This faster resolution trend supports the hypothesis that amphotericin B's mechanism—binding to ergosterol in the parasite membrane, causing increased permeability and rapid cell death—is more rapid in onset than the gradual inhibitory effects of SSG on parasite metabolism [17].

Both treatment groups showed minimal adverse events. Pain at the injection site was reported equally in both groups, which is expected given the nature of intralesional administration. Ulceration and erythema were mild and comparable between groups, findings consistent with those reported by Bumb et al. and other Indian authors [18][19]. Notably, systemic toxicity was absent in both groups, reinforcing the safety profile of localized therapy in CL, as emphasized in WHO treatment guidelines [20].

While systemic therapy with liposomal amphotericin B or oral miltefosine remains effective, an especially in complicated or mucocutaneous case, their use is limited by cost and potential toxicity. Intralesional therapy, on the other hand, provides a low-cost, well-tolerated, and localized treatment strategy suitable for resource-constrained settings, as supported by several regional and global studies [21][22].

The small sample size is a primary limitation of this study, which may reduce the statistical power to detect significant differences between groups. Moreover, long-term follow-up was not performed to assess relapse rates. Future multicentric, randomized controlled trials with larger samples and long-term surveillance are needed to better understand the comparative efficacy and safety of these agents.

In conclusion, both intralesional amphotericin B and SSG are effective and safe treatments for cutaneous leishmaniasis. However, the higher complete response rate and faster resolution observed with SSG may indicate its potential superiority, warranting further investigation.

Conflict of interest: Nil

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