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COMPARATIVE EFFICACY OF INTRAMUSCULAR MEGLUMINE ANTIMONIATE AND MILTEFOSINE IN THE MANAGEMENT OF CUTANEOUS LEISHMANIASIS

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ABSTRACT

Background: Cutaneous leishmaniasis is a frequent neglected parasitic skin disease in endemic areas, and can lead to chronic ulcers, disfigurement, scarring and psychosocial impacts. The standard injectable drug is meglumine antimoniate and the oral drug is miltefosine which is easier to administer. Local comparative data on their clinical effectiveness, however, are still very scarce.

Objective: To compare the efficacy of intramuscular meglumine antimoniate and oral miltefosine in the management of cutaneous leishmaniasis.

Methods: This non-randomized controlled trial was carried out in the Department of Dermatology, MTI Khyber Teaching Hospital, Peshawar from October 2025 to April 2026. The total number of cutaneous Leishmaniasis patients were 126 and they were sampled consecutively in non-probability sampling and divided into two equal groups. Group A was given intramuscular meglumine antimoniate and Group B was administered oral miltefosine for 4 weeks. The effectiveness of the treatment was determined at the end of the treatment and was defined as the clinical improvement of 90% or more, including the flattening of the lesion, re-epithelialization of the ulceration and disappearance of the induration. The analysis of data was done with SPSS version 24.

Results: Effective treatment response was observed in 48 (76.2%) patients in the meglumine antimoniate group and 36 (57.1%) patients in the miltefosine group. The difference between the two groups was statistically significant (p=0.023). Injection site pain was more common with meglumine antimoniate, whereas nausea and vomiting were more frequent with miltefosine.

Conclusion: Intramuscular meglumine antimoniate showed better short-term efficacy than oral miltefosine in patients with cutaneous leishmaniasis. However, treatment selection should consider efficacy, adverse effects, route of administration, and patient preference.

KEYWORDS: Cutaneous leishmaniasis, meglumine antimoniate, miltefosine, treatment efficacy, dermatology, Leishman-Donovan bodies.

INTRODUCTION

Cutaneous leishmaniasis (CL) is a disease of neglected tropics, caused by a protozoan parasite of the genus Leishmania. Usually occurs on exposed areas of the body like the face, upper and lower limbs and is spread by infected female sandflies. Typically, disease starts at the site of the bite as a small papule or nodule which may gradually develop into an ulcer with elevated margins and crusted centre. While the infections from Leishmania donovani are generally not fatal, they can cause chronic skin lesions, secondary infection, permanent scarring, cosmetic deformity and psychological distress especially when lesions are present on body parts which are visible (1-3).

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There are a number of treatment options for CL, but the best treatment is not yet agreed upon. Therapy is determined by a variety of factors: type of parasite, number and location of lesions, duration of lesions, availability of drugs, safety of the drug, the cost of treatment, patient compliance, and treatment response at the local level. Pentavalent antimonials

have been employed for many years and continue to be an important treatment option in certain endemic areas, such as meglumine antimoniate. These drugs work in many patients but must be given by injection, and can have side effects like injection site pain, myalgia, gastrointestinal symptoms, and possibly liver, kidney, or heart damage (7-9). Miltefosine is an oral antileishmanial drug which has come into limelight due to its ease of administration as compared to injectable antimonials. Orally administered, it could enhance patient compliance and diminish the frequency of re-hospitalisations. But it may not be as effective as in other parts of the world, as it may give gastrointestinal side effects, and is contraindicated in pregnancy. Miltefosine has been reported to have good therapeutic efficacy in some studies, but lower cure rates than antimonial therapy in others (10-12).

In local clinical practice, both meglumine antimoniate and miltefosine are used for the treatment of cutaneous leishmaniasis, but comparative data from the local population are limited. Since treatment response may vary according to regional parasite characteristics and patient-related factors, local evidence is needed to guide therapeutic decision-making. Therefore, the present study was conducted to compare the efficacy of intramuscular meglumine antimoniate and oral miltefosine in the management of cutaneous leishmaniasis at a tertiary care dermatology unit in Peshawar.

MATERIALS AND METHODS

This non-randomized controlled trial was conducted in the Department of Dermatology, MTI Khyber Teaching Hospital, Peshawar, from October 2025 to April 2026. The study was carried out after approval of the synopsis by the College of Physicians and Surgeons Pakistan, Research Evaluation Unit, under reference number CPSP/REU/DER-2023-020-19365, dated October 15, 2025. Ethical approval was also obtained from the Institutional Research and Ethical Review Board of Khyber Medical College/Khyber Teaching Hospital, Peshawar, vide approval No. 295/DME/KMC, dated March 28, 2025. All procedures were performed according to ethical principles, and confidentiality of patient information was maintained throughout the study.

A total of 126 patients of CL were enrolled in the study. Each group had 63 patients. The patients were selected sequentially, using non-probability sampling, from the dermatology outpatient clinic. Informing the patients about the purpose, procedure, expected benefits and possible side effects of the treatment, all patients who met the selection criteria were included. Prior to entering into the study, written informed consent was obtained from each participant.

Individuals, aged 18 to 60 years, of both sexes were included. Enrolled only confirmed cases of CL. The diagnosis was confirmed by clinical presentation and microscopic examination by identification of Leishman-Donovan bodies from samples taken from suspected skin lesions. Patients with typical skin lesions (papules, nodules or ulcers with raised margins and central crater) were evaluated for inclusion. Patients with liver disease, renal disease, pregnancy or hypersensitivity to meglumine antimoniate or miltefosine were excluded from the study.

Baseline data was taken after enrollment and was collected on a structured proforma. The data collected consisted of age, gender, BMI, place of residence, socioeconomic status, educational status, occupational status, lesion morphology, lesion site and treatment group. Lesion morphology (plaque, nodule or ulcer) and lesion site (lower limb, upper limb or head and neck area) were determined. Treatment side-effects were also noted such as pain at the site of the injection, nausea, vomiting or any other side-effect.

Patients were allocated consecutively into two treatment groups. Patients who were given intramuscular meglumine antimoniate constituted group A. After intradermal skin test dose, the drug was administered at a dose of 15–20 mg/kg/day for a total of 4 weeks. Patients who were given oral miltefosine were included in group B. In total, patients received 50 mg/day for 7 days and then 50 mg 3 times daily for 3 weeks, for a duration of 4 weeks. Patients were monitored periodically throughout treatment to measure clinical responses and to note any side-effects.

Treatment efficacy after 4 weeks of treatment was the primary outcome of the study. The efficacy was determined by achieving 90% or greater clinical improvement measured as a flattened lesion and re-epithelialization of ulcerated skin and absence of induration. Clinical assessment was carried out with a consultant dermatologist (at least 5 years post fellowship). Patients that reached the required clinical improvement were classified as “effective” treatment response; patients that did not reach the above defined criteria were classified as “ineffective” treatment response.

The data were entered and analysed using IBM SPSS version 24. The quantitative variables were age and the body mass index (BMI) and were reported as mean and standard deviation or median and interquartile range, depending on the normality of the data. The normality of the data was tested with the Shapiro-Wilk test. Qualitative variables like gender, residence, socio-economic status, education, occupation, lesion morphology, lesion site, side effects and treatment efficacy were reported as frequencies and percentages. The chi-square test or Fisher's exact test was used to measure the effectiveness of the treatment between the two groups as appropriate. Possible effect modifiers, such as age, gender, lesion site, lesion morphology, and side effects, were subjected to a stratification analysis. Post-stratification chi-square or Fisher's exact test was used. The p value was considered statistically significant if ≤ 0.05.

RESULTS

A total of 126 patients were included in the study with cutaneous leishmaniasis and were divided into two treatment groups. Intramuscular meglumine antimoniate were given to 63 patients in Group A and oral miltefosine were given

to 63 patients in Group B. Patients' age was 34.8 ± 11.6 years. Majority of patients were males, rural areas and lesions were primarily located on upper and lower limbs.

Table 1. Baseline demographic characteristics of the study participants

Variable	Group A: Meglumine Antimoniate n=63	Group B: Miltefosine n=63	Total n=126	p-value
Age, mean ± SD	35.2 ± 11.4	34.5 ± 11.8	34.8 ± 11.6	0.735
18–30 years	24 (38.1%)	26 (41.3%)	50 (39.7%)	0.713
31–45 years	27 (42.9%)	25 (39.7%)	52 (41.3%)	
46–60 years	12 (19.0%)	12 (19.0%)	24 (19.0%)	
Male	40 (63.5%)	38 (60.3%)	78 (61.9%)	0.710
Female	23 (36.5%)	25 (39.7%)	48 (38.1%)	
BMI, mean ± SD	24.1 ± 3.2	23.8 ± 3.4	23.9 ± 3.3	0.611
Urban residence	21 (33.3%)	23 (36.5%)	44 (34.9%)	0.705
Rural residence	42 (66.7%)	40 (63.5%)	82 (65.1%)	
Literate	35 (55.6%)	33 (52.4%)	68 (54.0%)	0.721
Illiterate	28 (44.4%)	30 (47.6%)	58 (46.0%)	
Employed	37 (58.7%)	35 (55.6%)	72 (57.1%)	0.720
Unemployed	26 (41.3%)	28 (44.4%)	54 (42.9%)	

Both groups of treatment were similar in baseline characteristics. The age, gender, BMI, place of residence, education level and occupation status were not significantly different between the two groups, A and B, indicating that both groups were comparable at the beginning of the treatment.

Table 2. Clinical characteristics of cutaneous leishmaniasis lesions

Variable	Group A: Meglumine Antimoniate n=63	Group B: Miltefosine n=63	Total n=126	p-value
Lesion duration, weeks, mean ± SD	7.4 ± 2.1	7.6 ± 2.3	7.5 ± 2.2	0.611
Plaque	18 (28.6%)	20 (31.7%)	38 (30.2%)	0.832
Nodule	17 (27.0%)	16 (25.4%)	33 (26.2%)	
Ulcer	28 (44.4%)	27 (42.9%)	55 (43.7%)	
Lower limb lesion	29 (46.0%)	27 (42.9%)	56 (44.4%)	0.888
Upper limb lesion	22 (34.9%)	23 (36.5%)	45 (35.7%)	
Head and neck lesion	12 (19.0%)	13 (20.6%)	25 (19.8%)	

The most frequently observed morphology was ulcerative, with plaque and nodular lesions being the next most common. The lower limb was the most common location, the upper limb ranked second, and the head/neck region ranked third. There were no differences between the two groups in terms of lesion morphology, location of the lesion or mean duration of lesion.

Table 3. Comparison of treatment efficacy between both groups after 4 weeks

Treatment outcome	Group A: Meglumine Antimoniate n=63	Group B: Miltefosine n=63	p-value
Effective treatment response	48 (76.2%)	36 (57.1%)	0.023
Ineffective treatment response	15 (23.8%)	27 (42.9%)	

The clinical efficacy after 4 weeks of treatment was 48 (76.2%) in the meglumine antimoniate group and 36 (57.1%) in the miltefosine group. The difference between the two groups was statistically significant showing that intramuscular meglumine antimoniate was more effective in short-term treatment of CL than oral miltefosine.

Table 4. Clinical improvement components after treatment

Clinical improvement parameter	Group A: Meglumine Antimoniate n=63	Group B: Miltefosine n=63	p-value
Flattening of lesion	51 (81.0%)	40 (63.5%)	0.028
Re-epithelialization of ulcer	47 (74.6%)	35 (55.6%)	0.025
Disappearance of induration	49 (77.8%)	37 (58.7%)	0.021

Overall ≥90% clinical improvement	48 (76.2%)	36 (57.1%)	0.023

Patients receiving intramuscular antimoniate exhibited significantly more flattening of the lesions, re-epithelialization and disappearance of induration than those receiving oral miltefosine when individual clinical response parameters were evaluated. The clinical improvement in Group A was significantly higher than in Group B (90% or more).

Table 5. Comparison of side effects between both groups

Side effect	Group A: Meglumine Antimoniate n=63	Group B: Miltefosine n=63	p-value
No side effect	31 (49.2%)	42 (66.7%)	0.047
Pain at injection site	22 (34.9%)	0 (0.0%)	<0.001
Nausea/vomiting	6 (9.5%)	17 (27.0%)	0.011
Other side effects	4 (6.3%)	4 (6.3%)	1.000
Any side effect	32 (50.8%)	21 (33.3%)	0.047

Side effects were more common in the meglumine antimoniate group than the miltefosine group. Only injection site pain was reported in Group A, whereas nausea and vomiting was more common in Group B. Meglumine antimoniate was more effective, but had a greater incidence of side effects.

Table 6. Stratification of treatment efficacy according to selected variables

Variable	Group A Effective / Total	Group B Effective / Total	p-value
Age 18–30 years	19/24 (79.2%)	16/26 (61.5%)	0.171
Age 31–45 years	21/27 (77.8%)	14/25 (56.0%)	0.096
Age 46–60 years	8/12 (66.7%)	6/12 (50.0%)	0.408
Male	31/40 (77.5%)	22/38 (57.9%)	0.064
Female	17/23 (73.9%)	14/25 (56.0%)	0.194
Ulcerative lesion	20/28 (71.4%)	14/27 (51.9%)	0.136
Plaque lesion	15/18 (83.3%)	13/20 (65.0%)	0.198
Nodular lesion	13/17 (76.5%)	9/16 (56.3%)	0.221
Lower limb lesion	22/29 (75.9%)	15/27 (55.6%)	0.112
Upper limb lesion	18/22 (81.8%)	14/23 (60.9%)	0.122
Head and neck lesion	8/12 (66.7%)	7/13 (53.8%)	0.513

In all age groups, genders, lesion morphology and lesion sites, a higher efficacy rate was consistently observed in the meglumine antimoniate group as compared to the other groups after stratification. However, some comparisons of the subgroups were not statistically significant, likely because there were fewer patients in each subgroup. In summary, the results indicate that after 4-weeks' therapy, intramuscular meglumine antimoniate is more effective than oral miltefosine for achieving clinical improvement in CL. Meglumine antimoniate did, however, have an increased risk of side effects, including pain at injection site.

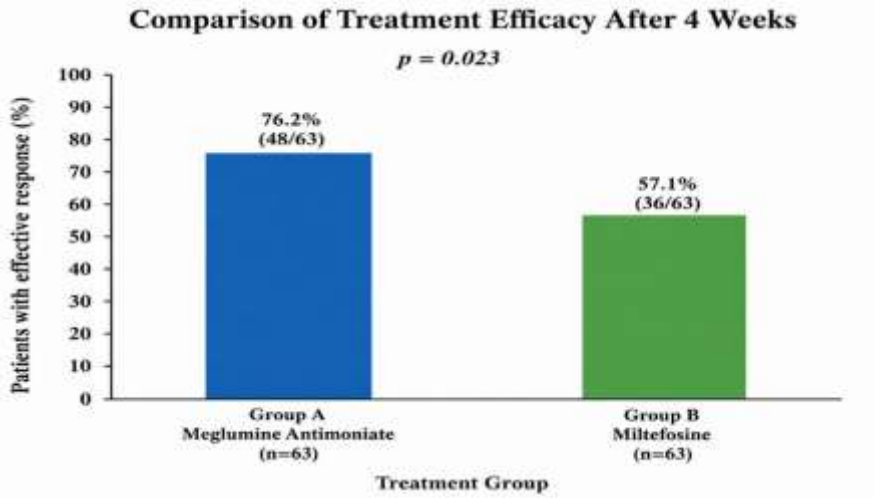

Figure 1. Comparison of treatment efficacy between intramuscular meglumine antimoniate and oral miltefosine after 4 weeks in patients with cutaneous leishmaniasis.

The figure shows that effective treatment response was higher in **Group A: intramuscular meglumine antimoniate** 48/63 (76.2%) compared with **Group B: oral miltefosine** 36/63 (57.1%). The difference was statistically significant (**p = 0.023**).

DISCUSSION

Cutaneous leishmaniasis is an important dermatological problem in endemic regions and remains a challenge because of its chronic course, cosmetic impact, treatment-related adverse effects, and variable response to available therapies. In the present study, intramuscular meglumine antimoniate showed a higher clinical efficacy than oral miltefosine after 4 weeks of treatment. Effective treatment response was observed in 76.2% of patients receiving meglumine antimoniate compared with 57.1% of patients receiving miltefosine, and this difference was statistically significant. These findings suggest that meglumine antimoniate remains an effective treatment option for cutaneous leishmaniasis in the local clinical setting (13-16).

The observed superiority in the treatment of Leucocutaneous leishmaniasis with meglumine antimoniate can be attributed to its proven anti-leishmanial activity and the long use in the treatment of Leucocutaneous leishmaniasis. Although they have been found to have acceptable clinical cure rates in various studies, pentavalent antimonials remain in use in many endemic areas, as they directly attack the parasite. The present study demonstrates that the meglumine antimoniate group showed a higher rate of flattening of lesions, re-epithelialization and disappearance of induration in early clinical healing. This is consistent with previous reports in which antimonial compounds have been described as effective first-line treatment for localized cutaneous leishmaniasis, but with varying responses depending on the species of the Leucocytozoon, length of illness, immune status of the host and compliance with the treatment (17, 18).

The benefits of miltefosine are that it is administered orally and for this reason it is often more convenient than an injectable treatment for patients. In the present study, its effectiveness was less than meglumine antimoniate following 4 weeks of treatment. This could be because of diversity in drug susceptibility between the Leishmania species found in the local population, differences in absorption or because it may take a longer time to observe the complete healing. Other previous trials have also revealed mixed results with miltefosine in treating cutaneous leishmaniasis, with some displaying improved cure rates and others reduced cure rates when compared to antimonial treatment (19). The use of Miltefosine is therefore a helpful alternative when injectable therapy is not possible, but its activity needs to be considered with reference to the local epidemiology and patient-specific considerations.

The safety and tolerability are key factors to consider when choosing treatment for C. leishmaniasis. Side effects were observed more often in the meglumine antimoniate group (mainly due to injection site pain) than in the miltefosine group (mainly due to nausea and vomiting) in the present study. This is due to the different safety profiles of the two drugs. Meglumine antimoniate is parenteral, may cause local pain and systemic side effects, while miltefosine is easier to administer orally but can cause gastrointestinal symptoms. Thus, efficacy should not be the sole criterion for treatment choice; patient preference, tolerance, contraindications, pregnancy status, and follow-up should be taken into account (20).

The clinical significance of the present study is in comparing two therapeutic regimens for which the patients were suffering from CL. The results corroborate the notion of the continued use of meglumine antimoniate as superior short term therapy in the population studied. In selected patients, however, miltefosine could still be considered, especially for those who are not able to take injections or have difficulty making frequent visits to the hospital. A relationship between effectiveness and side-effect must be maintained in clinical practice and various factors such as administration, side-effects, cost and compliance with the treatment must be taken into account (21).

In conclusion, there are certain limitations in this study. This study was carried out in one tertiary care hospital only and results may not be applicable to all endemics. Although performed consecutively, the study was non-randomized, and may have allocation bias. Follow-up was only done at 4 weeks, and follow-up results of complete cure, relapse, recurrence or any residual scarring were not evaluated. Species identification was also not conducted for Leishmania, as this could have an impact on treatment response. Further multicenter randomized trials with longer follow-up, identification of parasite species and determination of rates of relapse is recommended to confirm these findings and to support treatment plans in endemic areas.

CONCLUSION

Intramuscular meglumine antimoniate was more effective than oral miltefosine in achieving clinical improvement after 4 weeks of treatment in patients with cutaneous leishmaniasis. Patients receiving meglumine antimoniate showed higher rates of lesion flattening, re-epithelialization, and disappearance of induration compared with those receiving miltefosine. However, meglumine antimoniate was associated with more treatment-related side effects, especially injection site pain, while miltefosine was mainly associated with gastrointestinal symptoms. Therefore, meglumine antimoniate may be considered a more effective short-term treatment option, whereas miltefosine may remain an alternative for patients in whom injectable therapy is unsuitable. Further studies with larger sample sizes and longer follow-up are recommended to assess sustained cure and relapse rates.

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