

Original Article

Efficacy Of Intralesional Ciprofloxacin In Cutaneous Leishmaniasis As Compared To Intralesional Meglumine Antimoniate

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Institutional Review Board Approval

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Abstract

Objective: Cutaneous leishmaniasis (CL), a neglected tropical disease, poses a significant therapeutic challenge in endemic regions. Although intralesional meglumine antimoniate (MA) remains a standard treatment, its drawbacks necessitate the exploration of safer and, cheaper alternatives. This within-patient comparative study aimed to evaluate the efficacy of intralesional 0.2% ciprofloxacin compared with that of intralesional meglumine antimoniate in the treatment of CL.

Methods: A six-month comparative study was conducted at the Dermatology Department of a tertiary care hospital in, Malir Cantt, Karachi. A total of 128 patients with confirmed cutaneous leishmaniasis were enrolled. Only patients presenting with at least two lesions located on the contralateral sides of the body were included. Right-sided lesions were treated with intralesional 0.2% ciprofloxacin (Group A), whereas while left-sided lesions received intralesional meglumine antimoniate (Group B). Injections were administered every fifth day until re-epithelialization commenced. The primary outcome was the proportion of lesions achieving a complete clinical response (>75% reduction in size without induration) at eight weeks post-treatment initiation.

Results: The mean age of the participants was 30.6 ± 7.1 years, with a male predominance (78.9%). The complete response rate was 88.3% (113/128) in the ciprofloxacin group and 91.4% (117/128) in the meglumine antimoniate group. The difference in efficacy was not statistically significant (p-value = 0.486). Stratification by demographic and clinical variables revealed no significant differences in response rates across any subgroup.

Conclusion: Intralesional ciprofloxacin demonstrated comparable efficacy to that of intralesional meglumine antimoniate in the treatment of cutaneous leishmaniasis. Given its lower cost and favorable safety profile, ciprofloxacin may be a viable alternative therapeutic option, particularly in resource-constrained settings.

Keywords: Cutaneous Leishmaniasis; Ciprofloxacin; Meglumine Antimoniate; Injections, Intralesional; Treatment Outcome.

Introduction

Leishmaniasis, a vector-borne disease caused by obligate intracellular protozoan parasites of the genus *Leishmania*, persists as one of the most consequential neglected tropical diseases worldwide.¹ It is transmitted via the bite of infected female sandflies and exhibits a range of clinical symptoms, from self-resolving cutaneous ulcers to severe mucocutaneous lesions and potentially lethal visceral involvement.^{2,3} Ranked as the third most significant vector-borne illness globally, it presents a considerable public health challenge, with an estimated 700,000 to 1.2 million new cases of cutaneous leishmaniasis (CL) reported each year.^{4,5} The disease is prevalent in Pakistan, with recurrent reports from areas such as Baluchistan, Interior Sindh, Punjab, and Khyber Pakhtunkhwa, impacting susceptible communities and exacerbating local morbidity and social stigma.^{6,7} The management of CL is complex and fraught with challenges. There is no universal treatment, and the optimal therapeutic strategy must be tailored to the infecting *Leishmania* species, geographic region, and patient-specific factors.⁸ For decades, pentavalent antimonials, such as meglumine antimoniate, have constituted first-line

therapy in many endemic areas and are still considered standard treatment.⁹ Despite their efficacy, their use is limited by significant drawbacks, including systemic toxicity, the necessity for parenteral administration, cost, and rising concerns about parasite resistance.¹⁰ These limitations underscore the critical need for safer, more accessible, and cost-effective alternative therapies.

In this context, the fluoroquinolone antibiotic ciprofloxacin has emerged as a promising candidate. In addition to its antibacterial properties, ciprofloxacin has demonstrated direct anti-leishmanial activity in several studies.¹¹ Its potential as a cheaper, readily available, and well-tolerated intralesional agent offers a compelling alternative to antimonials. While a previous study by Arshad *et al.* in 2011 reported promising results, showing response rates of 84.38% for intralesional ciprofloxacin versus 93.33% for meglumine antimoniate, comparative data remain scarce.¹² Therefore, this study was designed to directly compare the efficacy of intralesional ciprofloxacin with that of standard intralesional meglumine antimoniate in the treatment of cutaneous leishmaniasis. By employing a within-patient comparative design to control individual variations in immune response, this research aims to provide robust, contemporary evidence to guide clinical practice and potentially offer a valuable new therapeutic option for patients with this neglected disease.

Materials And Methods

This comparative study was performed during six months, from July to December 2024, at the Dermatology Department of a Tertiary Care Hospital in Malir Cantt, Karachi. The Ethical Review Committee of the hospital approved the study (110/2023/Trg/ERC), and informed consent was obtained from all participants before enrolment. A total of 128 individuals with cutaneous leishmaniasis ulcers were recruited using a non-probability convenience sampling method. The sample size of 128 was determined using OpenEpi software, employing a two-sided significance level of 90% and a power of 80%, based on previously documented response rates of 84.38%,¹² for intralesional ciprofloxacin and 68.0%¹⁰ for intralesional meglumine antimoniate.

Patients of both sexes, aged 20 to 50 years, with a confirmed diagnosis of cutaneous leishmaniasis presenting with at least two lesions located on the contralateral sides of the body and manifesting as non-healing ulcers of at least two months of duration were recruited for this study. Both patients with a single ulcer and those with multiple ulcers (up to three per side) were included, provided they had at least one active lesion on the right side and at least one on the left side, as the within-subject design required bilateral involvement for simultaneous comparison of the two treatments. The diagnosis was established based on clinical presentation and the demonstration of *Leishmania* amastigotes in Giemsa-stained slit-skin smears. Patients were excluded if they had more than three lesions, any single lesion exceeding 5 cm in diameter, facial lesions, a history of specific antileishmanial treatment in the preceding month, any significant comorbidity, or an unwillingness to participate.

A within-subject comparison design was employed, in which each patient served as their own control to eliminate inter-patient variability in immune response. Right-sided lesions in all patients (Group A) were treated with intralesional injections of 0.2% ciprofloxacin. Contralateral lesions on the left side of the same patient (Group B) were treated with intralesional meglumine antimoniate (Glucantime). Both medications were administered intralesionally following a standard protocol, with injections repeated every five days until re-epithelialization was observed. The primary outcome was efficacy, defined as the proportion of lesions achieving a complete clinical response. Treatment response was assessed eight weeks after the initiation of therapy, and a complete response was defined as >75% reduction in lesion size with the absence of induration; a partial response was defined as 25–75% reduction in lesion size with persistent induration; and in case of <25% reduction in lesion size with persistent induration, no response was observed. For the analysis, "efficacy" was defined as the achievement of a complete response.

Demographic characteristics and clinical features were collected using a structured proforma. Data analysis was conducted utilizing the Statistical Package for the Social Sciences (SPSS), Version 25. Descriptive statistics are presented as mean \pm standard deviation for continuous variables and as frequencies and percentages for categorical variables. The Shapiro-Wilk test was employed to evaluate the normality of the data distribution. The chi-square test or Fisher's exact test was employed to assess the efficacy between the two treatment groups, with a p-value of ≤ 0.05 being statistically significant. Effect modifiers, including sex, age, and lesion location, were accounted for via post-stratification analysis.

Results

A total of 128 patients with cutaneous leishmaniasis ulcers were enrolled, and the mean age of the participants was 30.6 \pm 7.1 years (range, 20–50 years). Most patients (55.5%) were in the 20–30-year age group. The study population was predominantly male (78.9%). The mean duration of the disease was 2.1 \pm 1.6 months, with most patients (85.9%)

having a disease duration of 0–3 months. The mean number of ulcers per side was 1.2 ± 0.4 , and the mean maximum diameter of the ulcers was 2.0 ± 0.8 cm for both treatment groups. The most common sites for ulcers were the lower (42.2%) and upper limbs (36.7%). The complete baseline demographic and clinical characteristics are presented in Table 1.

The primary outcome of complete clinical response was achieved in 113 (88.3%) patients treated with intralesional ciprofloxacin (Group A) and in 117 (91.4%) patients treated with intralesional meglumine antimoniate (Group B). This difference in efficacy was not statistically significant ($p = 0.486$). The distribution of treatment responses is shown in Figure 1.

To control for potential confounding factors, the efficacy of both treatments was stratified across various demographic and clinical variables. As shown in Table 2, there was no statistically significant difference in the complete response rates between intralesional ciprofloxacin and meglumine antimoniate across any subgroup, including sex, age, residence, disease duration, or ulcer site ($p > 0.05$). This consistent lack of significant difference further reinforces the finding that the two treatments are comparable in efficacy.

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants (n=128)

Characteristic	Category	Frequency	Percentage
Gender	Male	101	78.9%
	Female	27	21.1%
Age Group (Years)	20-30	71	55.5%
	31-40	42	32.8%
	41-50	15	11.7%
Residence	Rural	52	40.6%
	Urban	76	59.4%
Duration of Disease	0-3 months	110	85.9%
	3-6 months	18	14.1%
Site of Ulcer	Neck	7	5.5%
	Abdomen	12	9.4%
	Chest	8	6.3%
	Upper Limbs	47	36.7%
	Lower Limbs	54	42.2%

Table 2: Stratified analysis of complete response rates by patient subgroups

Stratification Variable	Category	Complete Response, Group A (%)	Complete Response, Group B (%)	P-Value
Gender	Male	89/101 (88.1%)	95/101 (94.1%)	0.138
	Female	24/27 (88.9%)	22/27 (81.5%)	0.704
Age Group (Years)	20-30	64/71 (90.1%)	67/71 (94.4%)	0.532
	31-40	35/42 (83.3%)	39/42 (92.9%)	0.312
	41-50	14/15 (93.3%)	11/15 (73.3%)	0.329
Residence	Rural	46/52 (88.5%)	48/52 (92.3%)	0.741
	Urban	67/76 (88.2%)	69/76 (90.8%)	0.597
Disease Duration	0-3 months	98/110 (89.1%)	100/110 (90.9%)	0.653
	3-6 months	15/18 (83.3%)	17/18 (94.4%)	0.602
Ulcer Site	Neck	7/7 (100%)	7/7 (100%)	1.000
	Abdomen	12/12 (100%)	11/12 (91.7%)	1.000
	Chest	7/8 (87.5%)	7/8 (87.5%)	1.000
	Upper Limbs	43/47 (91.5%)	46/47 (97.9%)	0.361
	Lower Limbs	44/54 (81.5%)	46/54 (85.2%)	0.605

Group A: Intralesional Ciprofloxacin; Group B: Intralesional Meglumine Antimoniate

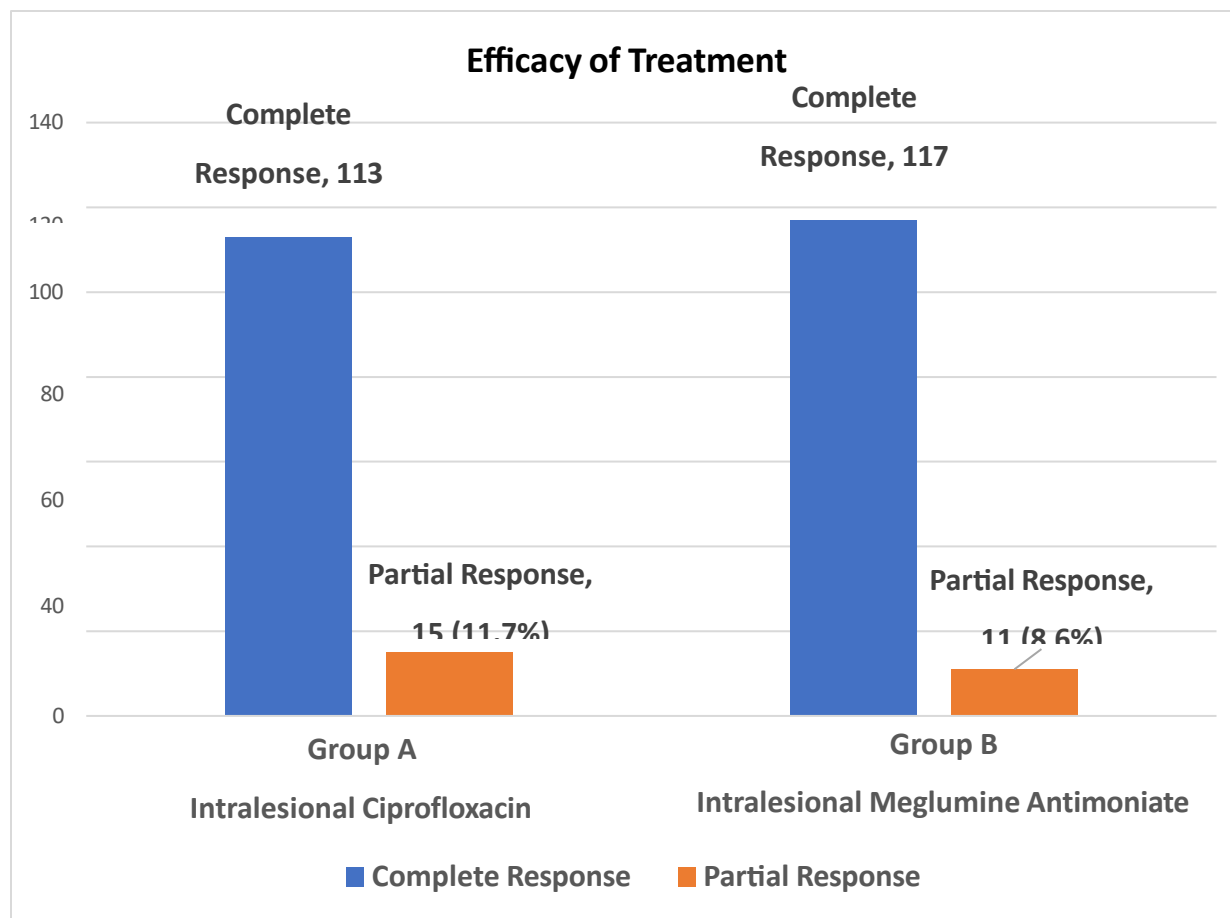


Figure 1: Graphical presentation of outcome among both study arms (n=128)

Discussion

This comparative study demonstrates that intralesional ciprofloxacin is a highly effective therapeutic option for the management of cutaneous leishmaniasis (CL), showing no statistically significant difference in efficacy when compared with standard treatment, intralesional meglumine antimoniate. The complete clinical response rates of 88.3% for ciprofloxacin and 91.4% for meglumine antimoniate ($p=0.486$) establish ciprofloxacin as a viable and potent alternative.

The high efficacy of meglumine antimoniate observed in our study aligns with its established role as a first-line therapy in many endemic regions. Our finding of a 91.4% cure rate is consistent with, and in some cases, superior to, rates reported in other studies. For instance, Arshad et al. reported a 93.33% response rate, while Mapar et al. and Brito et al. reported rates of 81% and 68.0%, respectively.^{12,13} The variability in response rates can be attributed to differences in *Leishmania* species, regional parasite resistance, and study protocols.

More significantly, the efficacy of intralesional ciprofloxacin in our cohort (88.3%) was remarkably high. This finding robustly supports the growing body of evidence that positions ciprofloxacin as an effective antileishmanial agent. Our results are in close agreement with those of Arshad et al., who reported an 84.38% response rate for ciprofloxacin.¹² Furthermore, studies by Al Hamdi et al. have affirmed its utility, reporting healing rates of 81.5% with 0.2% ciprofloxacin and a treatment success rate of 84.6%.^{14,15} The consistent performance of ciprofloxacin across these studies, including our own, underscores its reliability. The lack of a statistically significant difference in our within-subject comparison design, which inherently controls for individual immune response variations, provides particularly strong evidence for the non-inferiority of ciprofloxacin.

The implications of this finding are substantial for clinical practice, especially in resource-limited settings where CL is endemic.¹⁶ Pentavalent antimonials, such as meglumine antimoniate, are effective but are associated with significant drawbacks, including systemic cardiotoxicity, the requirement for parenteral administration, non-availability, and higher cost.¹⁷ Ciprofloxacin, a readily available and inexpensive antibiotic, presents a compelling

alternative. Its use could potentially reduce treatment costs, minimize systemic adverse effects, and improve access to effective care, thereby enhancing the quality of life for patients with this disfiguring disease.¹⁸

The robustness of our primary finding is further reinforced by the results of the stratification analysis. The comparable efficacy between intralesional ciprofloxacin and meglumine antimoniate remained consistent across all subgroups analyzed, including sex, age, residence, disease duration, and ulcer site (all p-values > 0.05). This uniformity indicates that the treatment effect was not modified by these common demographic and clinical variables, as described in a few previous studies.¹⁹ For instance, the efficacy of ciprofloxacin was not diminished in subgroups that might be associated with different healing responses, such as older patients or those with longer disease duration. The consistent lack of statistical significance across these diverse strata powerfully substantiates the conclusion that the two therapies are equally efficacious in a broad patient population with cutaneous leishmaniasis ulcers.

This study has several limitations. First, the use of a non-probability convenience sampling method may limit the generalizability of the findings. Second, the study was conducted at a single center. Future multi-center studies with random sampling would be valuable in confirming these results. Third, the study did not specify the *Leishmania* species; it is known that different species can exhibit varying susceptibilities to treatment. Finally, long-term follow-up to assess scar quality and recurrence rates was beyond the scope of this study.

Conclusions

This study provides compelling evidence that intralesional ciprofloxacin is not inferior to standard intralesional meglumine antimoniate in achieving complete clinical healing of cutaneous leishmaniasis ulcers. The comparable high efficacy rates, reinforced by a robust within-patient study design, firmly establish ciprofloxacin as a potent therapeutic agent against this disease. Consequently, intralesional ciprofloxacin should be considered an effective and accessible alternative, especially in clinical scenarios where antimonials are contraindicated, poorly tolerated, or economically prohibitive for the patient. Its adoption into clinical practice could significantly improve treatment access and outcomes in endemic regions.

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