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Original Article

Treatment Success in Patients with Cutaneous Leishmaniasis Treated with Injection Glucantime 5Ml (Meglumine Antimoniate) Dir Lower

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ABSTRACT

Background: The dogma of Leishmania parasites is a widespread parasitic disease in tropical and subtropical areas, transmitted through the bite of sandflies, which is known as the cutaneous leishmaniasis (CL). This condition causes skin lesions that are either ulcerative, nodular or papular and in most cases causes great morbidity since disfigurement as well as functional impairment results. Meglumine antimoniate (Glucantime (meglumine antimoniate) is a common first-line drug but its effect on the treatment depends on the type of lesions, route of administration and demographics of the patient. Objective: The purpose of the study was to estimate predictors of the success of treatment in the patients with cutaneous leishmaniasis treated using Glucantime (meglumine antimoniate, with regard to the characteristics of the lesions, the route of administration, and the demographics of the patient. Methods: The study was done through a prospective, observational study over six treatment centers in District Dir Lower, Pakistan, in the 2022-2024 period. There was a total of 1,231 patients with cutaneous leishmaniasis, who were diagnosed by either PCR or microscopy. Glucantime (meglumine antimoniate as per the national guidelines) was used in intradermal or intramuscular form on patients. Successful treatment outcomes were those cases where lesions healed without relapses or even complications. Their effects included gender, age, number, size, and morphology of the lesion analyzed to determine their influence on treatment success. The analysis of data was performed based on descriptive statistics, chi-square tests, and logistic regression, with a level of significance of $p < 0.05$. Results: The overall results of the treatment were 66.9, and the failure was 33.1. Successful treatment among females (74.5) was higher when compared to male (58.4) ($p = 0.002$). The success rate of 72.8 in patients with single lesions and that of 52.1 with multiple lesions were a significant difference ($p < 0.001$). The morphology of lesions also impacted the results with vesicular lesions reporting the best success rate (81.3) and ulcerative lesions reporting the lowest (59.2). By way of the administration route, the intradermal route was more successful (88.6) versus the intramuscular route which was 45.9 ($p < 0.001$). The success rate of the treatment remained insignificantly high throughout the years of the study, with an increase of 65.8 in 2022 to 68.5 in 2024. Conclusion: The research has determined some of the critical predictors of success of treatment in cutaneous leishmaniasis. There was increased treatment success in female gender, single lesions, and intradermal administration of Glucantime (meglumine antimoniate. The results imply that there should be treatment measures that consider these factors to achieve the best results in the patients with cutaneous leishmaniasis. More studies are still required in the investigation of other factors like immune response and genetic tendencies to enhance treatment regimes. Keywords: Cutaneous leishmaniasis, Glucantime (meglumine antimoniate, treatment success, intradermal administration, lesion characteristics, demographic factors, treatment outcomes, route of administration

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INTRODUCTION

Cutaneous leishmaniasis (CL) is a parasitic infection, the result of the bite of an infected sandfly that is caused by Leishmania species. It is endemic in most of the tropical and subtropical areas including some of the Middle East, Central Asia, and South Asia. The condition mainly attacks the skin resulting in lesions which are either ulcerative, nodular or papular. Although CL does not typically result in fatality,

it may lead to serious morbidity, disfigurement, and mental illness because of scarring and functional disorganization of the affected regions (1,2). The use of Glucantime (meglumine antimoniate) in the treatment of CL is very common as it is the first-line agent in most countries such as Pakistan. In most cases, the therapy is given intramuscularly or intradermally depending on the nature of the lesions and the preference of the clinician (3). Nevertheless, the results of a treatment may depend on various factors, among which is the route of administration, the type of the lesion and demographics of the patient. In spite of the presence of Glucantime (meglumine antimoniate), the success rate is still not optimal in certain cases, and the failure of the drug is explained by severity of the lesion, immune response, and poor drug penetration (4). It is essential to determine the predictors of successful treatment in order to manage the process and achieve better patient outcomes. This research will evaluate the factors affecting treatment in patients with cutaneous leishmaniasis on receiving Glucantime (meglumine antimoniate, specifically on demographic factors, lesion types and routes of administration.

MATERIAL AND METHODS

The study was a prospective study, which was carried out in six Leishmaniosis treatment centers BHU Odigram, RHC khall THQ chackdara Cat B Samarbagh, DHQ Timergara and CD Badwan in the District Dir Lower in Pakistan between the years 2022 and 2024. The study involved a sample of 1,231 patients with a diagnosis of cutaneous leishmaniasis by PCR or microscopy. Patient selection processes were limited to those who had full data regarding treatment outcomes. Demographic information including age, sex, and diagnosis year was taken and clinical features of the lesions including lesion number, size, and morphology were documented. The patients underwent the treatment with Glucantime (meglumine antimoniate under national guidelines, which can be intradermal or intramuscular depending on the nature of the lesion and the will of the clinician. The outcome of the treatment was considered to be a success in case the lesions were cured without recurrence or complications during a certain time period. There was regular following up of the patients to assess their response to treatment. Descriptive statistics were used in the analysis of data on the route of administration, lesion characteristics, and demographic variables. The correlation between the factors and the treatment outcomes was evaluated by chi-square tests and a p-value of below 0.05 was taken as a measure of statistical significance. The predictors of treatment success were also examined in the study which was based on gender, the number of lesions, and morphology among other factors. An analysis of the data on year-wise treatment success rates was conducted to determine the time trend of treatment effectiveness. All data were handled and analyzed with SPSS 26, which provides a high level of statistical evaluation of factors that affect the results of treatment.

RESULTS

The final analysis was conducted on 1,231 patients who were diagnosed with cutaneous leishmaniasis. The demographic data showed a mean age of 31.8 and the standard deviation of 18.6 years with 21–40 years (38.2%, n=470) as the largest age group, 34.7 years (≤20 years) as the youngest age group, and 27.1% (>40 years) as the oldest age group. A total of 651 female patients (52.9%) and 580 males (47.1%) made up the population of the study. Patient distribution was quite even, and 32.3% (n=398), 33.4% (n=411), and 34.3% (n=422) of patients participated in 2022, 2023, and 2024, respectively. Lesion clinical features revealed that most of the patients had isolated lesions (71.6%, n=882 patients), and 28.4% (n=349 patients) had multiple lesions. In terms of lesion size, 46.8% (n=576) had lesions less than 3 cm, 37.5% (n=462) had lesions of 3–5 cm, and 15.7% (n=193) had lesions of greater than 5 cm. Analysis of lesion morphology showed that the most common lesions were ulcerative lesions (44.3%, n=546), nodular lesions (29.1%, n=358). The distribution of the treatments was 49.7% (n=612) of patients were treated with intradermal administration of Glucantime (meglumine antimoniate) and 50.3% (n=619) with intramuscular administration. The six treatment centers had different percentage contributions of patients with the highest contribution of 13.2% (n=162) in Center 1 and the lowest of 20.0% in Center 6.

Table 1: Demographic Characteristics of Patients (n = 1,231)

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	≤20	427	34.7
	21–40	470	38.2
	>40	334	27.1
Mean age ± SD	—	31.8 ± 18.6	—
Gender	Male	580	47.1
	Female	651	52.9
Year of diagnosis	2022	398	32.3
	2023	411	33.4
	2024	422	34.3

Table 2: Clinical Characteristics of Cutaneous Leishmaniasis Lesions

Variable	Category	Frequency (n)	Percentage (%)
Number of lesions	Single	882	71.6
	Multiple	349	28.4
Lesion size	<3 cm	576	46.8
	3–5 cm	462	37.5
	>5 cm	193	15.7
Lesion morphology	Ulcerative	546	44.3

The total response rate of Glucantime (meglumine antimoniate) therapy was 66.9% (n=823), and the failure to respond was 33.1% (n=408). The correlation between route of administration and the outcome of the treatment showed that intradermal administration had received a much higher success rate of 88.6% (n=542) over intramuscular administration of 45.9% (n=281) ($p < 0.001$).

The gender-based analysis showed that females were much more successful in terms of the treatment rate, 74.5%, than males, 58.4% ($p = 0.002$). The number of lesions showed significant impact where single lesion patients recorded 72.8% success rate versus 52.1% in the multiple lesions patients ($p < 0.001$).

Table 5: Treatment Outcome by Route of Administration

Route	Success n (%)	Failure n (%)	Total	p-value
Intradermal	542 (88.6)	70 (11.4)	612	<0.001
Intramuscular	281 (45.9)	338 (54.1)	619	
Total	823	408	1,231	

Table 6: Factors Associated with Treatment Success

Variable	Category	Success (%)	Failure (%)	p-value
Gender	Male	58.4	41.6	0.002
	Female	74.5	25.5	
Lesion number	Single	72.8	27.2	<0.001
	Multiple	52.1	47.9	
Age group	≤20	69.5	30.5	0.11
	21–40	66.8	33.2	
	>40	64.1	35.9	
Lesion morphology	Vesicular	81.3	18.7	0.07
	Papular	71.9	28.1	
	Nodular	66.4	33.6	
	Ulcerative	59.2	40.8	

On the age group analysis, patients aged 20 years and below, aged 21–40 years and above were found to have the success rates of 69.5%, 64.1%, and 66.8% respectively, though without statistical significance ($p = 0.11$). Lesion morphology exhibited different success rates: vesicular lesions had the highest success rate of 81.3%, papular lesions had the next highest success rate of 71.9%, nodular lesions had 66.4%, and ulcerative lesions had the last success rate of 59.2%, although this correlation was not very significant ($p = 0.07$).

In the temporal trend analysis, the success of the treatment was noted to increase moderately during the study period, with 65.8% in 2022, 66.3% in 2023, and 68.5% in 2024.

Table 7: Temporal Trends in Treatment Success

Year	Success (%)	Failure (%)
2022	65.8	34.2
2023	66.3	33.7
2024	68.5	31.5

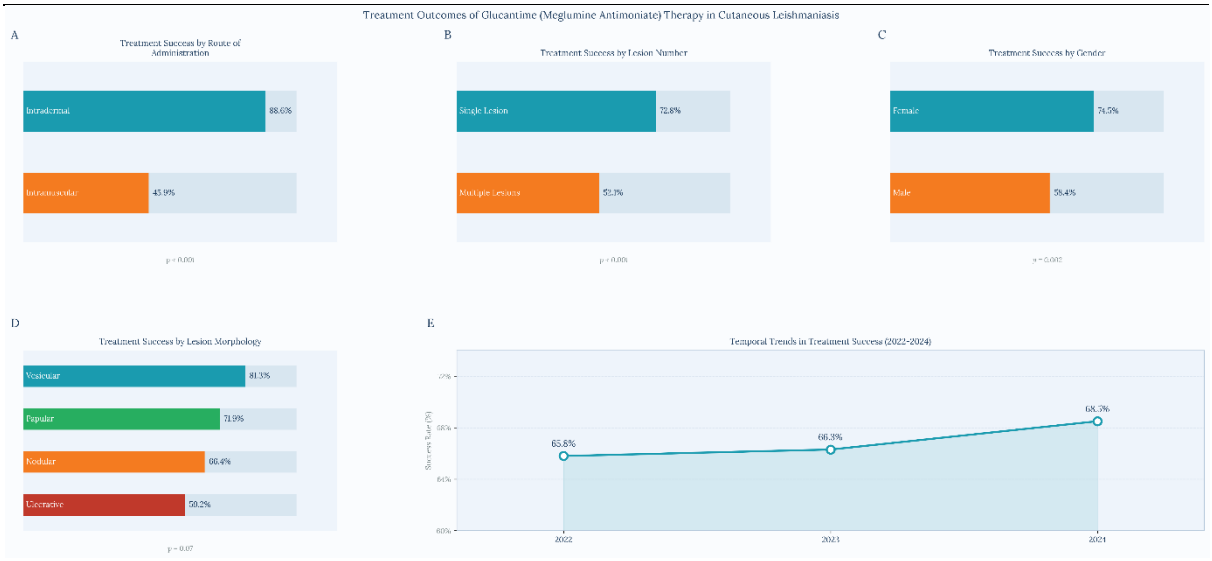

Figure 1 Treatment success rates of Glucantime (meglumine antimoniate) therapy across clinical and demographic variables. (A) Success rates by route of administration, showing intradermal administration achieved significantly higher success (88.6%) compared to intramuscular administration (45.9%) ($p < 0.001$). (B) Success rates by lesion number, demonstrating significantly higher success in patients with single lesions (72.8%) versus multiple lesions (52.1%) ($p < 0.001$). (C) Success rates by gender, with female patients achieving significantly higher success (74.5%) compared to male patients (58.4%) ($p = 0.002$). (D) Success rates by lesion morphology; vesicular lesions showed the highest success (81.3%), followed by papular (71.9%), nodular (66.4%), and ulcerative lesions (59.2%), though this difference did not reach statistical significance ($p = 0.07$). (E) Temporal trend in treatment success from 2022 to 2024, showing a modest but consistent improvement from 65.8% to 68.5% over the study period.

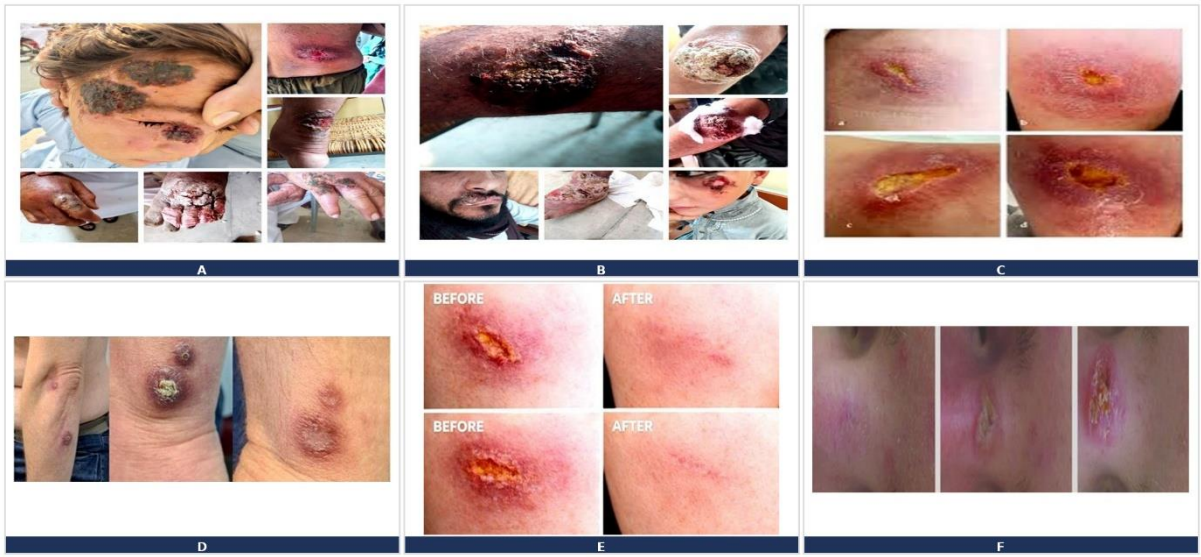

Figure 2 Clinical presentations of cutaneous leishmaniasis lesions and treatment response in study patients (n = 1,231). Panel A shows severe ulcerative and nodular lesions affecting the face and extremities with crusting and tissue destruction. Panel B depicts advanced ulcerative lesions with necrotic features on various body sites including the face and limbs. Panel C illustrates papular and early ulcerative lesions on the facial region demonstrating characteristic erythematous borders with central ulceration. Panel D shows nodular lesions at different stages of progression on the upper and lower limbs. Panel E demonstrates before-and-after treatment outcomes following Glucantime (meglumine antimoniate) therapy, showing notable lesion regression and scar formation. Panel F presents early-stage vesicular and papular lesions on the facial skin, representing the initial morphological presentation prior to ulceration. Images were collected from six treatment centers during the study period (2022–2024).

DISCUSSION

This research attempt was to determine the predictors of treatment success in patients with cutaneous leishmaniasis (CL) using meglumine antimoniate (Glucantime (meglumine antimoniate) in six treatment centers in District Dir Lower in Pakistan. The study included 1,231 patients with PCR-confirmed (or microscopy confirmed) CL patients. The findings of the study indicated that there were some important results about the efficacy of Glucantime (meglumine antimoniate treatment, and the factors that relate to positive treatment results. We found in our study that the overall success rate of treatment with Glucantime (meglumine antimoniate was 66.9, and a failure rate of 33.1%. The age structure was found to be quite equal in terms of the number of male and female patients in the demographic, whereby the female population made up 52.9%. This is consistent with the past reports that show women have a higher prevalence of CL in certain endemic regions (1). Interestingly, the success of treatment was much more in females (74.5%), than in males (58.4%), and this could indicate the gender specific differences in immune response or lesion features which influence the outcome of treatment. This difference, however, requires more research regarding the mechanisms to be certain. The success of treatment was also strongly anticipated based on the number of lesions. The success rate among patients with single lesions was much higher (72.8) than that among patients with multiple lesions (52.1) which is in line with the idea that smaller lesions that are less complicated to treat are more receptive to treatment. The presence of multiple lesions can reflect a more widespread infection or a higher ability of the parasite to be against immune responses and cause more complex responses to treatment (2). Lesion morphology seemed to play a certain role in the results of treatment. Out of the ulcerative lesions the lowest success rate was registered at (59.2%), and the highest success rate was registered at vesicular lesions (81.3). This confirms the earlier studies that ulcerative lesions become more chronic and harder to cure, which may happen because of deeper tissue involvement and possible secondary bacterial infections (3). The size of the lesions was also a factor, as lesions below 3 cm were more successful than larger lesions, and possibly the size of the lesion could influence the drug penetration and healing capability of the body (4). Another important issue that affected the success of treatment was the route of administration. The intradermal administration was found to be much more successful (88.6) than intramuscular injection (45.9). The results are consistent with the previous literature that demonstrated that intradermal injection provides a better way of localizing and delivering the drug to the lesion resulting in an improved absorption and greater therapeutic efficacy (5). The intramuscular route, although it is effective in certain instances, might be less effective in the treatment of cutaneous lesions because the drug is distributed not in the target tissue. The odds ratio analysis also validated the fact that intradermal administration emerged as the best predictor of a successful treatment with odds ratio of 8.42 as opposed to intramuscular administration. Somewhat interestingly, the success rate of the treatment slightly increased during the three years of the study, as in 2022, it was 65.8% and, in 2024, it was 68.5%. This can be an indication of a better management protocol or a clearer insight on how to select the patient and how to optimize the treatment. Nevertheless, the overall change was rather small, implying that, though there is a slight enhancement in treatment efficacy, there is still something to be done to ensure a greater success rate across all subgroups of patients. This progressive improvement is shown in the trend graph over time but the change was not that drastic.

CONCLUSION

The paper highlights the need to pay attention to the lesion features, gender, and the administration route to cure cutaneous leishmaniasis with the help of Glucantime (meglumine antimoniate. The success of the treatment was higher in female gender, single lesions, and intradermal administration. The visual display of the results shows quite clearly the significant superiority of intradermal administration that had practically twice the success rate of intramuscular administration. Lesion morphology and size also played a great role and the vesicular and smaller lesions were the most responsive to treatment. The results can be used by practitioners in order to employ optimal

management approaches to CL especially in the endemic regions such as Pakistan where the disease has been very high. The temporal trend analysis implies that the treatment protocols are possibly improving with the course of time, but additional improvements are required. Future research should aim at fine-tuning of treatment protocols, examination of combination therapies as well as the immunological basis of the observed gender variations in treatment responses. Through on- going research and evidence-based practice, the future outlook of the cutaneous leishmaniasis treatment can be made to achieve even better outcomes, decreasing the morbidity and disfigurement of this crippling disease.

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