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# Efficacy of Oral Terbinafine with Meglumine Antimoniate/ Glucantime (Intalesional) vs Glucantime I/L alone in Treatment of Cutaneous Leishmaniasis

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## ABSTRACT

**Introduction:** Leishmaniasis is a chronic vector-born protozoan disease, occurring in various presentations from the self-limiting, even self healing cutaneous nodular or ulcerated lesion to lifethreatning visceral disease, each caused by one of the species of the genus leishmania. It is the major health problem worldwide. It also appears to be an emerging disease in the various parts of Pakistan especially in rural areas& endemic in Bolochistan, Interior Sindh, Multan, Tribal area (refugees from Afghanistan) & western border of Pakistan.

**Objective:** To compare the efficacy of oral terbinafine with meglumine antimoniate/(Glucantime) intralesional verses Glucantime (intralesional) alone for treatment of cutaneous Leishmaniasis.

**Methodology:** This Randomized control trails study was carried out at the Dermatology Department Lady Reading Hospital Peshawar for duration of six months from June 2023 to November 2023. In this study a total of 102 patients were included by taking 51 in each group, using 80% efficacy of oral Terbinafine + Glucantime, 52.9% efficacy of Glucantime alone, 95% confidence level & 90% power of test (Non Probability Sampling) technique was used for sample collection.

**Results:** Our study shows that in Group A mean age was 33 years with SD ± 3.621 and in Group B mean age was 32 years with SD ± 3.315. In Group A 68% patients were male and 32% patients were female. Where as in Group B 65% patients were male and 18(35%) patients were female. Group A (oral terbinafine 250 mg daily + Glucantime I/L) was effective in (82%) patients where as Group B (Glucantime I/L once) was effective in (60%) patients.

**Conclusion:** Our study concludes that oral terbinafine with Glucantime (intralesional) was more effective as compare to Glucantime (intralesional) alone for treatment of cutaneous Leishmaniasis

**Keywords:** *efficacy, intralesional meglumine antimonite injections, cutaneous leishmaniasis.*

## INTRODUCTION

Leishmaniasis is a chronicvector-born protozoan disease1, occurring in various presentation from the self-limiting, even self healing cutaneous nodular or ulcerated lesion to lifethreatning visceral disease ,each caused by one of the species of the genus leishmania2.

It is the major health problem worldwide.2 It also appears to be an emerging disease in the various part of Pakistan specially in rural areas& endemic in Bolochistan, Interior Sindh, Multan ,Tribal area (refugees from Afghanistan) & western border of Pakistan3. According to WHO estimates,approximately 1.5 million new casesof cutaneous leishmaniasis &500,000 cases of visceral leishmaniasis per year are usuallyseen& the overall prevalence is about 12million worldwide1,while the major bulk of cases arereported 90% from Afghanistan, Iran, Iraq, Algeria. Saudi Arabia, Peru&Pakistan.3 In most part of the world, Pentavalent antimonials compounds including Meglumine antimoniate(Glucantime) & Sodium stibogluconate are .

regarded as first- line treatment or drug of choice for cutaneous leishmaniasis.4It kills leishmania species by DNA fragmentation& by process of apotosis.5 These drugs can cause important & severe adverse effects on the heart,kidney,liver & pancreas also and a cause local reaction in form of thrombophlibitis, phlebitis & edema at site of IV administration.3,5 Moreover the clinical resistance is also seen in at least 40% of cases in certain region3

Among the potential alternatives, the antifungal drugs i.e. terbinafine (allylamine antifungals) whichappears to be effective via oral administration[6]. It is the squaline oxidase inhibitor& thus inhibit theergosterol synthesis which lead to interruption of delivery of cholesterol & ergesterol to the leishmania parasite membrane which have high % of ergesterol in it and also inducing autophagic process within parasite via producing multivesiclar bodies in the parasite cell matix.[7] According tothestudy, done at Iran in 2011, which result shows that 80% of complete cure seen in patient who received oral terbinafine along with glucantime while 52.9 % complete cure seen in patient who received gulcantime alone.[6]However the case report & pilot study on role of terbinafine also shows its effectiveness against cutaneous leishmaniasis.[8,9] Over the past few years pentavalent antimonials is becoming less , so there is need to discover newer agent orally administered with fewer side effects, effective, cheap which should be added to this traditional therapy to prevent its complications & higher doses requirement.[10] The rationale of our study is to evaluate the response of adding oral terbinafine with glucantime in terms of complete cure of lesion,reduce the time of healing process & decrease the dosage requirement of glucantime to prevent its complication.

## MATERIAL AND METHODS

This Randomized control trails study was carried out at the Dermatology Department Lady Reading Hospital Peshawar for duration of six months from June 2023 to November 2023. Sample size was 51 patients in each group using 80% efficacy of oral Terbinafine + Glucantime, 52.9% efficacy of Glucantime alone, 95% confidence level & 90% power of test. Non probability consecutive method was used in our study. The inclusion criteria was all the patients of both gender and age more than 18-60 years with No of Lesion 1 to 3, Size of Lesion < or = 3 cm, Parasititology confirmed Lesion of CL, No significant concomitant disease, Patient with normal blood counts &normal liver and renal function tests while exclusion criteria was all the patients with No of Lesion more than 4, Lesion size more than 5 and Patient with liver & renal diseases.

The study was conducted after getting approval from hospital ethical & research committee. All patients meeting the inclusion criteria were included in the study through OPD. The purpose & benefit of study was explained to the patients & they were assured that the study is done purely for data publication & research purpose & written & informed concerned was obtained. All patients were subjected to detailed history & clinically examination & were randomly allocated into 2 groups by lottery methods. Patients in group A was subjected to oral terbinafine 250 mg daily + Glucantime I/L once weekly for 6 weeks. While patients in group B was subjected to only in Glucantime I/L once weekly for 6 weeks. The results were assessed at base line & at the 6 weeks after starting the treatment. The response was evaluated by healing of lesion i-e the clinical improvement in form of Re-epthilization & atleast 50% reduction in size & induration ( flatting) of lesion relative to previous observation at the end of 6$^{th}$ week after starting treatment.[11] All the observation that was the clinically improvement of Lesion was conducted under supervision of single expert having minimum of 5 years experience. All of the above information including name, age, and gender was recorded in a predesigned Performa. Data was analyzed in SPSS version 24. Mean +SD was calculated for numerical like age, no of lesions, size of lesion, induration (height) of lesion at presentation. Frequencies and percentages were calculated for categorical like gender and efficacy. Chi square test was applied to compare the efficacy in two groups. P value of less than or equal to 0.05, was considered statistically significant.

## RESULTS

This study was conducted at Dermatology Department Lady Reading Hospital Peshawar in which 51 patients in each group to compare the efficacy of oral terbinafine with Glucantime (intralesional) Group A verses Glucantime (intralesional) Group B alone for treatment of cutaneous Leishmaniasis and the results were analyzed as:

Age distribution among two groups was analyzed as in Group A 24(47%) patients were in age range 20-30 years, 17(33%) patients were in age range 31-40 years, 8(15%) patients were in age range 41-50 years, 2(5%) patients were in age range 51-60 years. Mean age was 33 years with SD ± 3.621. Where as in Group B 23(45%) patients were in age range 20-30 years, 18(35%) patients were in age range 31-40 years, 8(15%) patients were in age range 41-50 years, 2(5%) patients were in age range 51-60 years. Mean age was 32 years with SD ± 3.315. (table no 1)

Gender distribution among two groups was analyzed as in Group A 35(68%) patients were male and 16(32%) patients were female. Where as in Group B 33(65%) patients were male and 18(35%) patients were female (table no 2)

Number of lesions among two groups was analyzed as in Group A 37(72%) patients had less than 2 lesions while 14(28%) patients had more than 2 lesions. Mean number of lesions were 2 with SD ± 1.81. Where as in Group B 36(70%) patients had less than 2 lesions while 15(30%) patients had more than 2 lesions. Mean number of lesions were 2 with SD ± 1.87. (table no 3)

Size of lesions among two groups was analyzed as in Group A 38(75%) patients had lesion ≤2 cm while 13(25%) patients

had lesions >2 cm. Mean size lesions were 1.8 cm with SD ± 1.55. Where as in Group B 39(77%) patients had lesion ≤ 2 cm while 12(23%) patients had lesions >2 cm. Mean size lesions were 1.9 cm with SD ± 1.74. (table no 4)

Induration of lesion among two groups was analyzed as in Group A 34(67%) patients had lesion height ≤ 1 cm while 17(33%) patients had lesions >1 cm. Mean lesions height was 1cm with SD ± 1.26. Where as in Group B 35(69%) patients had lesion height ≤ 1 cm while 16(31%) patients had lesions >1 cm. Mean lesions height was 1cm with SD ± 1.30. (table no 5)

Efficacy among two groups was analyzed as Group A (oral terbinafine 250 mg daily + Glucantime I/L) was effective in 42(82%) patients and was not effective in 9(18%) patients. Where as Group B (Glucantime I/L once) was effective in 31(60%) patients and was not effective in 20(40%) patients. (table no 6)

**TABLE NO 1. AGE DISTRIBUTION**

| AGE | GROUP A | GROUP B |
|---|---|---|
| **20-30 years** | 24(47%) | 23(45%) |
| **31-40 years** | 17(33%) | 18(35%) |
| **41-50 years** | 8(15%) | 8(15%) |
| **51-60 years** | 2(5%) | 2(5%) |
| **Total** | 51(100%) | 51(100%) |
| **Mean and SD** | 33 year ± 3.621 | 32 year ± 3.315 |

T Test was applied in which P value was 0.1489

**TABLE NO 2. GENDER DISTRIBUTION**

| GENDER | GROUP A | GROUP B |
|---|---|---|
| **Male** | 35(68%) | 33(65%) |
| **Female** | 16(32%) | 18(35%) |
| **Total** | 51(100%) | 51(100%) |

Chi Square test was applied in which P value was 0.6744

**TABLE NO 3. NUMBER OF LESIONS**

| NO OF LESIONS | GROUP A | GROUP B |
|---|---|---|
| **≤ 2** | 37(72%) | 36(70%) |
| **>2** | 14(28%) | 15(30%) |
| **Total** | 51(100%) | 51(100%) |
| **Mean and SD** | 2 ± 1.81 | 2 ± 1.87 |

T Test was applied in which P value was 0.1000

**TABLE NO 4. SIZE OF LESIONS**

| Size of lesions | GROUP A | GROUP B |
|---|---|---|
| **≤ 2 cm** | 38(75%) | 39(77%) |
| **>2 cm** | 13(25%) | 12(23%) |

| | | |
|---|---|---|
| **Total** | 51(100%) | 51(100%) |
| **Mean and SD** | 1.8cm ± 1.55 | 1.9 cm ± 1.74 |

T Test was applied in which P value was 0.7599

**TABLE NO 5. INDURATION OF LESION**

| INDURATION OF LESION | GROUP A | GROUP B |
|---|---|---|
| **≤ 1 cm** | 34(67%) | 35(69%) |
| **>1 cm** | 17(33%) | 16(31%) |
| **Total** | 51(100%) | 51(100%) |
| **Mean and SD** | 1 cm ± 1.26 | 1 cm ± 1.30 |

T Test was applied in which P value was 0.1000

**TABLE NO 6. EFFICACY**

| EFFICACY | GROUP A | GROUP B |
|---|---|---|
| **Effective** | 42(82%) | 31(60%) |
| **Not effective** | 9(18%) | 20(40%) |
| **Total** | 51(100%) | 51(100%) |

Chi Square test was applied in which P value was 0.0158

**DISCUSSION**

Leishmaniasis is a parasitic infection that may lead to a variety of manifestations; Cutaneous leishmaniasis (CL) has a high prevalence. There are many treatment Modalities for CL. The use of oral terbinafine in the treatment of CL has recently been considered as additional therapy.[12]

Systemic pentavalent antimoniates have been used as the first line therapy of leishmaniasis for more than eighty years. Although, the drugs are effective about 30% but their adverse effects such as fatal cardiotoxicity, myalgia, pancreatitis, and elevated serum amylase, lipase and liver enzyme levels etc. limit their usage.[13]

Besides, their painful injections are another limitation of the drug, especially in children. Hence, presenting new methods to cure this neglected disease is considered in many investigations. However oral terbinafine in the treatment of CL is less cost effective than antimonite drugs and it is also non-invasive and safe. The aim of my study was to evaluate the response of adding oral terbinafine with Glucantime in terms of complete cure of lesion, reduce the time of healing process & decrease the dosage requirement of Glucantime to prevent its complication. According to the study, done at Iran in 2011, Ebrahimias [14] which results shows that 80% of complete cure seen in patient who received oral terbinafine along with Glucantime while 52.9 % complete cure seen in patient who received gulcantime alone. However the case report & pilot study on role of terbinafine also shows its effectiveness against cutaneous leishmaniasis.[15] While comparing to our study the results almost similar, has shown that the group A .i.e. combination of oral terbinafine and Glucantime intraregional (82%) is more effective and superior than Glucantime I/L alone (60%). As for as, demographical features are concerned the mean age of (patient) Abdullah F [16] was 30 years with SD + 2.331. This was consistent with my study and the mean age of patients in groups A&B was almost 33years with SD+3.621 and 32 years with SD+3.315 respectively.

However in our study patient presenting to us mostly males about 68% and 65% in group A & B respectively that is there is male preponderance this finding was similar in study by Moosavi Z.[17]

In another study Badamdan KA [8] efficacy of only oral terbinafine to treat CL was assessed. They found that the complete response was 34% while in my study the combination of oral terbinafine and Glucantime has much more good results which shows that synergistic effect of oral terbinafine along with Glucantime I/L. Mitropoulos P[10] demonstrated that antifungals ketoconazole and terbinafine compound could be effective on Leishmaniasis they compare two groups (control

and terbinafine groups) and terbinafine group was meaningfully treated. Our study finding has supported their results.

It was also seen in our study that adding oral terbinafine with Glucantime not only causes the complete cure of lesion, but also reduce the time of healing process & decrease the dosage requirement of Glucantime to prevent its complication. Another study done by Alotaibi H et al. also reported similar results.[18]

In the referral studies, it is also stated that the oral terbinafine is as effective as Glucantime but on other side it is al so cost effective, non invasive and safer than Glucantime and addition of it with Glucantime give more good results due to its synergistic effect. It also gives rapid healing and prevents the complications related to increase numbers of intraleisnal injections of Glucantime.[19, 20]

**CONCLUSION**

Our study concludes that oral terbinafine with Glucantime (intralesional) was more effective as compare to Glucantime (intralesional) alone for treatment of cutaneous Leishmaniasis..

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