



Research Article

INTRALESIONAL MEGGLUMINE ANTIMONIATE VERSUS PLASMA RICH PLATELETS: COMPARISON OF EFFICACY IN CUTANEOUS LEISHMANIASIS

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Abstract: Cutaneous Leishmaniasis (CL), associated with considerable morbidity, is still a major health problem in the world, especially in developing countries. The intralesional infiltration of meglumine antimoniate (MA) is considered among the standard therapies for the New World Leishmaniasis. Platelet-rich plasma (PRP) is a promising therapy in dermatology and aesthetic medicine. PRP is an autologous serum containing high concentrations of platelets and growth factors. It has been used in dermatology for the treatment of various ulcers with variable successful results. This study compares the efficacy of Intralesional PRP with Intralesional meglumine antimoniate in the treatment of CL. **OBJECTIVE:** To compare the efficacy of intralesional Meglumine Antimoniate and intralesional PRP in the treatment of CL. **STUDY DESIGN:** Cross-sectional; Prospective **DURATION OF STUDY:** 17-01-2020 to 16-07-2020 **DATA COLLECTION PROCEDURE:** A total of 60 participants with Cutaneous Leishmaniasis were equally divided among two groups randomly, one was treated with Intralesional Meglumine Antimoniate (group 1) and the other with Intralesional Platelet-rich Plasma (group 2). Group 1 patients were given intralesional meglumine antimoniate, Group 2 patients received intralesional PRP. Lesions were reassessed after 4 weeks. **RESULT:** Higher efficacy in the Intralesional Platelet-rich Plasma group was found in almost all the sub-groups of patients by demographic and disease characteristics such as age, gender, education status, socioeconomic status, duration of disease, site of lesion, number of lesions, size of lesion, and diagnosis. The efficacy rate was found to be significantly higher in Intralesional Platelet-rich Plasma (group 2) as compared to Intralesional Meglumine Antimoniate (group 1), with an efficacy rate of 86.7% (26) vs. 50% (15); $p=0.002$, respectively. **CONCLUSION:** Although this study showed a significantly better outcome in terms of treatment by PRP, but exact mechanism that leads to the resolution of parasitic infection needs to be studied at the molecular level as well.

Keywords: Leishmaniasis, Cutaneous Leishmaniasis (CL), Mucocutaneous Leishmaniasis (MCL), visceral Leishmaniasis (VL), Platelet-rich plasma (PRP)

INTRODUCTION

There are more than 20 species of the genus *Leishmania* causing a group of diseases known as leishmaniasis. The disease is transmitted to humans by the bites of the infected female sand fly. It has three major clinical forms: Cutaneous Leishmaniasis (CL), Mucocutaneous Leishmaniasis (MCL), and visceral Leishmaniasis (VL), which differ in immunopathologies and degree of morbidity and mortality. As per data by the WHO, Leishmaniasis is endemic in 98 countries, with 1.3 million new cases annually. The major burden of the disease is in Afghanistan, Algeria, Brazil, Colombia, Iran, Pakistan, Peru, Saudi Arabia, and Syria. CL is a rising epidemic and is an economic and health burden in almost all regions of Pakistan. It is a major public health problem in areas bordering Afghanistan and Iran. , , The first choice drug recommended by WHO is antimonial compounds, including meglumine antimoniate. It has a high cost, is not readily available, and many areas are now reporting resistance to these compounds. With all

these limitations, the reported efficacy of Intralesional meglumine antimoniate is 38.5%.

Platelet-rich plasma (PRP) is a newer treatment modality being studied for its role in healing chronic wounds related to its pro-angiogenic effects. As PRP is derived from a person's own blood, it is inherently safe in terms of immune reactions and infection transmission. , , PRP is used in dermatology in the treatment of various ulcers with successful results.^{7, 9}, Considering its effectiveness in different kinds of ulcers and its fewer side effects, we want to exploit its role in ulcers of Cutaneous Leishmaniasis as well. Since, according to our knowledge, no data is available for the efficacy of PRP in CL or any other infectious ulcers, this study compares the results of PRP and standard treatment with meglumine antimoniate in ulcers of CL. If the study shows the efficacy of PRP more than meglumine antimoniate, then it can be a good alternate treatment option for ulcers of CL.

OBJECTIVE: To compare the efficacy of intralesional Meglumine Antimoniate and intralesional PRP in the treatment of CL.

MATERIALS AND METHODS

STUDY DESIGN: Cross-sectional observational.

SETTING: Combined Military Hospital, Malir Cantt, Karachi.

DURATION OF STUDY: 17-01-2020 to 16-07-2020

SAMPLE SIZE: The Sample size was calculated by using the WHO sample size calculator. Efficacy in one group (Meglumine Antimoniate) i.e P1, is 38.5%, efficacy in the other group (PRP) i.e P2 is 93% from pilot study. Confidence interval 95%, Power of test 90%, level of significance 5%. Sample size of the study was 60, 30 in each group. Patients were assigned equally into both groups by lottery method.

SAMPLING TECHNIQUE: Non-probability consecutive sampling

SAMPLE SELECTION:

Inclusion Criteria: Patients who are diagnosed case of CL (as per operational definition). Patients between 14-70 years of age of either gender. Patients with 1-3 ulcerated lesions for less than 2 months.

Exclusion Criteria: Patients who had a history of taking anti-leishmanial therapy within the last two months, Pregnancy or lactation, known drug allergies to antimony compounds, lesions involving joints, anemia, leukocytosis, thrombocytopenia, thrombocytosis, and positive serology for Hepatitis B or C were excluded from the study.

RESULTS

A total of 60 patients with Cutaneous Leishmaniasis were treated with Intralesional Meglumine Antimoniate (group 1) and Intralesional Platelet-rich Plasma (group 2). Table 1 summarizes the findings of the study. Patients in group 2 were relatively younger than group 1, with a mean age of 28.63 ± 4.25 vs. 33.67 ± 7.95 ; $p=0.004$. The gender distribution was found to be similar between the treatment groups, with a male patients' proportion of 90% (27) vs. 100% (30), only three females participated in the study, and all belonged to the meglumine antimoniate groups, $p=0.795$. Educational status distribution was same between the two groups ($p=0.274$) with post-graduation patients' proportion of 46.7% (14) vs. 43.3% (13) and graduation patient's proportion of 36.7% (11) vs. 23.3% (7) in Intralesional Meglumine Antimoniate (group 1) and Intralesional Platelet-rich Plasma (group 2) respectively. The socioeconomic status distribution was also similar between the treatments groups ($p=0.0951$) with proportion of the patients' $>50k$ as 30% (9) vs. 33.3% (10) and 20-50k as 33.3% (10) vs. 33.3% (10) in Intralesional Meglumine Antimoniate (group 1) and Intralesional Platelet-rich Plasma (group 2) respectively. The duration of disease distribution was the same between the treatment groups, with a duration of ≤ 6 weeks in 70% (21) vs. 73.3% (22); $p=0.774$, in Intralesional Meglumine Antimoniate (group 1) and Intralesional Platelet-rich Plasma (group 2), respectively. The site of lesions distribution was also similar between the treatments groups ($p=0.0740$) with proportion of the patients' with hand/feet as 30% (9) vs. 36.7% (11) and lower limb as 53.3% (16) vs. 43.3% (13) in Intralesional Meglumine Antimoniate (group 1) and Intralesional Platelet-rich Plasma (group 2) respectively. The number of lesion distributions was found to be similar between the treatment groups, with a single lesion in 66.7% (20) vs. 66.7% (20); $p>0.999$, in Intralesional Meglumine Antimoniate (group 1) and Intralesional Platelet-rich Plasma (group 2), respectively. The size of lesion distribution was found to be similar between the treatment groups, with lesion length of 10.77 ± 4.37 cm vs. 8.53 ± 4.82 cm; $p>0.065$, in Intralesional Meglumine Antimoniate (group 1) and Intralesional Platelet-

DATA COLLECTION PROCEDURE: Before starting the study, approval by the hospital's ethical review committee was taken. Informed written consent was obtained from all participants of the study, according to the inclusion and exclusion criteria, at the Outpatient Department of Dermatology, Combined Military Hospital, Malir, Karachi. Data was collected using a proforma. The patients were divided equally into two groups by the lottery method. Group A was given intralesional meglumine antimoniate by dividing the lesion into four quadrants till blanching of the lesion, weekly for 6 weeks. Group B received intralesional PRP weekly for six weeks. Patients were called for follow-up after 4 weeks of therapy, and lesions were reassessed. A detailed history of the disease and clinical examination of the lesion were done. Any side effects reported by the patient during this period were carefully asked about and noted. During this period patient did not take any other treatment for CL. Baseline complete blood picture, HbsAg, and Anti-HCV were done. The cost of treatment was borne by the hospital. To reduce the biases and to overcome confounders, data was noted on a pre-designed proforma by the researcher herself, and at the end of the study, no missing data and no lost to follow-up were found.

DATA ANALYSIS PROCEDURE: For data analysis and results, SPSS Version 23 was used. Quantitative variables, including age and duration of therapy, were measured by mean and standard deviation, while qualitative variables like gender were calculated as frequency and percentage. Chi-square test was applied to compare the response to both treatments after 6 weeks. For controlling effect modifiers like age, gender, and duration of disease, stratification was done. Chi-square test was then applied to calculate the P value for each effect modifier.

rich Plasma (group 2), respectively. The diagnosis distribution was found to be similar between the treatment groups with smear in 33.3% (10) vs. 33.3% (10); $p>0.999$, in Intralesional Meglumine Antimoniate (group 1) and Intralesional Platelet-rich Plasma (group 2), respectively. The efficacy rate was found to be significantly higher in Intralesional Platelet-rich Plasma (group 2) as compared to Intralesional Meglumine Antimoniate (group 1), with an efficacy rate of 86.7% (26) vs. 50% (15); $p=0.002$, respectively. Efficacy rate was significantly higher in Intralesional Platelet-rich Plasma (group 2) as compared to Intralesional Meglumine Antimoniate (group 1) in almost most of the sub-groups of patients by their characteristics, as presented in Table 1.

Table 1: Rate Of Efficacy By Demographics In Treatment Groups:

		Group				P-value
		Meglumine Antimoniate		Platelet-rich plasma (PRP)		
		Efficacy		Efficacy		
		Yes	No	Yes	No	
Age Groups	Under 30 years	60% (6)	40% (4)	87.5% (14)	12.5% (2)	0.105
	30 to 45 years	45% (9)	55% (11)	85.7% (12)	14.3% (2)	0.016*
Gender	Male	51.9% (14)	48.1% (13)	86.7% (26)	13.3% (4)	0.543
	Female	33.3% (1)	66.7% (2)	0% (0)	0% (0)	-----
Education Status	Middle	20% (1)	80% (4)	90% (9)	10% (1)	0.007*
	Graduation	27.3% (3)	72.7% (8)	100% (7)	0% (0)	0.002*
	Post-Graduation	78.6% (11)	21.4% (3)	76.9% (10)	23.1% (3)	0.918
Socioeconomic Status	20k	45.5% (5)	54.5% (6)	100% (10)	0% (0)	0.006*
	20-50k	50% (5)	50% (5)	90% (9)	10% (1)	0.051*
	>50k	55.6% (5)	44.4% (4)	70% (7)	30% (3)	0.515
Duration	≤ 6 weeks	57.1% (12)	42.9% (9)	81.8% (18)	18.2% (4)	0.078
	> 6 weeks	33.3% (3)	66.7% (6)	100% (8)	0% (0)	0.004*
Site of lesion	Upper limb	20% (1)	80% (4)	66.7% (4)	33.3% (2)	0.122
	Lower limb	68.8% (11)	31.3% (5)	100% (13)	0% (0)	0.027*
	Hand/Feet	33.3% (3)	66.7% (6)	81.8% (9)	18.2% (2)	0.028*
No of lesion	Single Lesion	55% (11)	45% (9)	85% (17)	15% (3)	0.038*
	More than 1 Lesions	40% (4)	60% (6)	90% (9)	10% (1)	0.019*
Size of lesion	≤ 10 cm	50% (6)	50% (6)	85% (17)	15% (3)	0.033*
	>10 cm	50% (9)	50% (9)	90% (9)	10% (1)	0.034*
Diagnosis	Clinical	55% (11)	45% (9)	85% (17)	15% (3)	0.038*
	Smear	40% (4)	60% (6)	90% (9)	10% (1)	0.019*

DISCUSSION

Cutaneous leishmaniasis is a protozoal disease leading to ulcerated and scarring disease and deformities. For the past few decades, geographical prevalence has increased from the tropics only to worldwide distribution. CL is a complex protozoal disease with no identifiable ideal therapy to date. In most of the regions, the mainstay of treatment for CL is Parenteral Pentavalent Antimony (SbV). Despite their toxicity and need for frequent lab monitoring during the treatment, they are being used for the treatment. Frequent Lab monitoring and toxicity enhance the impact of financial burden of this disease. Because of these concerns, a relatively safe treatment requiring less monitoring with fewer side effects for CL was always sought. In 2010, the WHO Expert Committee on Leishmaniasis, for New World Leishmaniasis, recommended local treatment as an acceptable alternative. Advantages associated with local intralesional infiltration are lower total dose of the compound (hence lesser side effects) and thus decreased need for laboratory monitoring. Local infiltration of these compounds also does not need heavy budgeted equipment. Despite an extensive literature search, we

hardly came across much data for the efficacy rate of this therapeutic modality, i.e., intralesional administration. This study reproduced the same cure rate as that of parenteral antimony compound for the New World and is comparable to that for Old World in some systematic reviews. , , However a Turkish study comparing intralesional approach of the two compounds of antimony reported better efficacy (IL-MA 82% versus IL SS 67%), the possible explanation of these results include exclusive study of infections caused by *L. Major* and *L. Tropica* and the criteria of cure adopted by the researchers. In that retrospective study author assessed the cure rate after eight cycles of intralesional infiltrations, while in this study, the outcome was assessed after completion of all infiltrations in one or two cycles of infiltrations.

After a thorough data research, our discussion includes articles on different treatment options containing antimony compounds, but we could not find any study reporting the role of PRP as a treatment option for CL. PRP has been reported to treat many chronic disfiguring ulcers, but the role of PRP in the treatment of an infectious ulcer has never been reported to the best of our

knowledge. The main limitation of this study is the lack of randomization and single-centre study, but the study involved participants from different geographical areas of Pakistan.

CONCLUSION

Although this study showed a significantly better outcome in terms of treatment by PRP, but exact mechanism that leads to the resolution of parasitic infection needs to be studied at the molecular level as well. For this purpose, further research and Randomized controlled trials, including double-blinded studies, are needed for the validation of results, also, molecular level studies are needed to elaborate the pathophysiology leading to the resolution of an infected ulcer by PRP.

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