Original Article

Intralesional ciprofloxacin for cutaneous leishmaniasis: Comparison with meglumine antimoniate

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ABSTRACT

Objectives: Leishmaniasis is quite commonly encountered in Balochistan. Of all the known treatment modalities, only a few are available at our hospital. We carried out this study in search of an effective and easily available agent.

Methodology: This quasi-experimental study was carried out at Combined Military Hospital Sibi in Balochistan from May to Nov 2010. The gross appearance of non healing ulcers and demonstration of parasite in Giemsa stained smears were used to confirm the diagnosis. Thirty nine patients were enrolled and divided into two groups by non- probability convenience sampling. Eighteen patients (having 30 ulcers) received meglumine antimoniate and 21 patients (having 32 ulcers) received 0.2% ciprofloxacin intralesionally every fifth day till re-epithelialization started, up to a maximum of five doses. Side effects of therapy were checked at every visit. Patients were followed up at one week and subsequently one month after completion of treatment to assess complete clinical healing and regression in size of the scar.

Results: Two ulcers in meglumine antimoniate and five ulcers in ciprofloxacin group did not heal (response rate 93.33% vs. 84.38%, p: 0.273). Those treated with meglumine antimoniate required a lesser number of doses (mean 3.83 and 4.27; p: 0.039). Reduction in scar size was equal in both groups (58.46% and 57.21%; p: 0.087).

Conclusions: Intralesional ciprofloxacin is an effective, cheap and safe treatment for cutaneous leishmaniasis.

KEY WORDS: Leishmaniasis, Intralesional, Ciprofloxacin, Meglumine antimoniate.

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INTRODUCTION

Cutaneous leishmaniasis is commonly seen in Balochistan, particularly affecting the rural population. The disease runs a chronic indolent course; ulcers are ugly looking and often heal slowly to leave behind cosmetically disfiguring scars. The optimal treatment is still not clearly defined. However, a broad armamentarium of drugs is available to treat this disease, in oral, locally applicable and injectable forms. The latter which appear to be the most promising, can be given locally or systemically. Intralesional therapy is preferred because of fewer side effects and lower costs. Meglumine antimoniate (Glucantime®) remains the gold standard but not easily available at Sibi, which necessitates the use of

an alternative agent that is cheaper and more freely/consistently available. Ciprofloxacin is one such drug. Considering this, we carried out this study to assess the effectiveness of this agent in comparison with meglumine antimoniate.

METHODOLOGY

This quasi-experimental study was carried out at Combined Military Hospital Sibi from June to Nov 2010 after seeking approval from the hospital ethics committee. Serving soldiers with cutaneous leishmaniasis were enrolled from the outdoor clinic after they provided informed written consent. Diagnosis was established by a history of a non healing ulcer not responding to oral co-amoxiclav (used for one week); gross appearance of the ulcer and demonstration of parasite in Giemsa stained slit skin smears. Patients with more than three lesions, those with lesions more than 5cm diameter, those with lesions on the face and those who had received any specific treatment in the past were excluded.

History was taken focusing on the age, gender, occupation, location of residence, use of complementary medicine therapies and characteristics of the ulcers including their duration, number, location and size. Maximum diameter of the lesions in any axis was also measured, expressed as 'size' in data analysis. Non- probability convenience sampling technique was used to randomize the subjects to either of the two groups: the first one received meglumine antimoniate and the other 0.2% ciprofloxacin. Both the drugs were administered intralesionally using the standard technique. Treatment was repeated every fifth day till re-epithelialization started, upto a maximum of five doses. All injections were administered by a single physician to rule out any bias. At each encounter, side effects of therapy were also looked for, including any cutaneous reactions, secondary infection or regional lymphadenitis. Patients were followed up at one week and subsequently one month after completion of treatment to assess complete clinical healing. Size of the scar was measured at final visit to determine the decrease in size attributable to drug therapy. Those with non-healed ulcers at this stage were started on intramuscular meglumine antimoniate.

Data was analyzed with PASW Statistics 18. Student's t-test was used to compare the statistical significance of differences between the two groups.

RESULTS

We enrolled 39 male patients having 62 ulcers in total. The first group comprising of 18 patients with 30 ulcers was administered meglumine antimoniate, whereas the second group with 21 patients having 32 ulcers was treated with 0.2% ciprofloxacin. Both groups had similar patient ages, duration of illness, size and pattern of distribution of ulcers as shown in Tables-I and II.Two to five sessions were required for treatment of ulcers, with most requiring five. The frequencies depicted in Table-III reveal that a greater percentage of ulcers treated with ciprofloxacin required five doses as compared to those treated with meglumine antimoniate.

There were two treatment failures in the first group and 5 in the second. 28 out of the 30 ulcers treated with meglumine antimoniate and 27 out of the 32 ulcers treated with ciprofloxacin healed. This apparent difference was statistically insignificant (response rate 93.33% vs. 84.38%, p: 0.273). The mean reduction in sizes of scars was 58.46% with meglumine antimoniate and 57.21% with ciprofloxacin (p: 0.087). Apart from local pain at the time of injection, no side effect to therapy was observed in any of the patients. All the patients were compliant and none was lost to follow up.

DISCUSSION

Considering a wide range of treatment options available for cutaneous leishmaniasis, it is extremely important to choose the best one for any particular patient. This takes into account the available resources, patient preference and economic factors.

Table-I: Comparison between the two treatment groups.

Parameter	*Meglumine antimoniate*	*Ciprofloxacin*	*p value*
No of Patients	18	21	-
Number of ulcers	30	32	-
Age of patients (years)	26.42± 4.64	27.98± 6.32	0.083
Duration of illness (weeks)	3.46± 0.86	3.72± 1.44	0.213
Maximum diameter (cm)	2.01± 0.90	1.93± 1.11	0.612
Number of doses required (mean)	3.83	4.27	0.039
Response rate	93.3%	84.38%	0.273

Table-II: Anatomical distribution of ulcers.

Site	*Meglumine antimoniate group*	*Ciprofloxacin group*
Neck	0	1
Upper limbs	10	12
Abdomen	1	1
Chest	0	1
Lower limbs	19	17

Table-III: Treatment sessions required in both groups.

No. of sessions	*Ciprofloxacin group*	*Meglumine antimoniate group*
2	1	0
3	3	7
4	8	10
5	20	13

(Figures refer to the number of patients in each category)

In our hospital, the options are limited to systemic/ parenteral or intralesional pharmacological agents. Local treatment has several advantages over intramuscular route and is thus the treatment of choice.

A large number of studies on the use of intralesional meglumine antimoniate have been published so far. Response rates vary from 55%[1] to 97.2%.[2] Some of these have focused on meglumine antimoniate only whereas others have compared it with other treatment modalities including cryotherapy[3], intralesional hypertonic saline, zinc sulphate[4], paromomycin[5] and oral itraconazole.[6] For quite some time, we have been using meglumine antimoniate in our hospital but the supply of the drug is unpredictable and the agent is quite expensive as it is sold in black throughout the region. Ciprofloxacin, on the other hand, is cheap and consistently available. It appeared to be equally efficacious agent but there was no significant published scientific evidence in support. Our trial has proved that it is at least as effective as antimoniates if not better.

Our results are comparable with the 81.5% response rate to ciprofloxacin previously reported by AlHamdi et al.[7] Patients treated with ciprofloxacin required a larger number of doses and hence more visits to physician in contrast to those receiving meglumine antimoniate, possibly indicating slower onset of action of the drug. Scarring was seen in all of our patients, to an equal extent in both treatment groups. At the end of 4 weeks, the size was much smaller relative to the original lesion and the scar is expected to shrink further over time.

Female patients were not included in this trial merely because none reported to our clinic. This is possibly multifactorial. Poverty, careless attitude towards timely/ appropriate treatment and use of non-allopathic modalities (especially ointments of unknown composition made by local quacks) are possible contributors. Unfortunately, due to limited time period available, we could not follow up patients beyond one month of the last dose, and thus could not collect data regarding possible recurrence of the lesions. Besides this, another shortcoming of this study is the small sample size. More studies involving a larger number of patients/ lesions are required to strengthen the evidence base.

Extensive literature review on Pubmed, Open J-Gate and Google has failed to identify any study directly comparing meglumine antimoniate with ciprofloxacin for treatment of cutaneous leishmaniasis. This makes our study a unique one and perhaps the first of its kind ever reported.

CONCLUSION

Intralesional ciprofloxacin is as effective as intralesional meglumine antimoniate for treatment of cutaneous leishmaniasis and without any significant side effects. Its use should be encouraged because the cheap cost and easy availability make its use convenient.

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