



Research Article

Study on the Causes of Discontinue Treatment in Treated Patients with Cutaneous Leishmaniasis with Muscle Glucantime Injection based on the Type of Medicine (Treatment) Side Effects

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Abstract

Background and objective: Cutaneous leishmaniasis is considered as an endemic disease in not only Iran but also all over the world. Since cutaneous leishmaniasis is not mainly fatal, therefore it has not been considered seriously by researchers as such as fatal and hard diseases, therefore due to lack of studies in this area in Iran territory, Cutaneous leishmaniasis has been focused to be studied in the current study.

Methods: The current research is a cross-sectional descriptive-analytic study. The studied patients were the 54 cases who were the candidates of the treatment by systematic glucantime muscle injection in Sabzevar city at 2016 based on the country protocol. The relations among the parameters including demographic, systemic symptoms, pancreatic enzyme alterations, liver enzyme alterations, CBC, BUN, Cr by the incidence of complications during the 3-week treatment period were studied by systemic glucantime injection. To analyze the obtained data, Chi-squared test of SPSS program version 16 was applied.

Findings: Regarding the achieved results, 31 males (57.4%) and 23 females (42.6%) were selected as candidates of systemic treatment. 22 candidates (40.7%) were under the age of 60 years. Refractive index treatment was 50%, that all of the candidates have shown systemic complications with significant relations with incidence of time ($P < 0.0001$). 14.7% of the candidates along with systemic symptoms, showed enhancements in pancreatic enzymes 3 times high, presenting significant differences with incidence of time ($P < 0.006$). The highest complications occurred during the first week of treatment.

Results: In the present research, the causes of the treatment ending was the incidence of systemic complications and incremental changes in pancreatic enzymes due to glucantime muscle injection occurs mostly in the first weeks of treatment period that finally may lead to the use of alternative methods including cryotherapy for patients treatment.

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Keywords

Cutaneous leishmaniasis; Glucantime; Muscular injection; Systemic treatment

Introduction

Cutaneous Leishmaniasis is one of the endemic diseases in Iran and all over the world [1]. Salak disease has over than 20 different Leishmania species and is categorized among parasitic diseases. This disease is transmitted through the saliva of a mosquito-infested substance. This disease has exposed over than 350 million people to this infection and more than 1.3 million people have got infected by this disease, moreover 20-30 thousands death is recorded annually due to this disease. The clinical symptoms of this disease are local ulcers (Cutaneous leishmaniasis) to systemic lethal diseases (Visceral leishmaniasis). Cutaneous Leishmaniasis rate is growing since this disease has not been considered for studies extensively by scientists; this phenomenon may be due to its non-fatal property [2]. Some of the reported negative effects by this disease are chronic making its treatment gets difficult such as when Cutaneous Leishmaniasis leads to skin cancer [3]. Leishmaniasis type dermal (cutaneous) is one of the most considerable health issues of Eastern Mediterranean Regional Office (EMRO) [4]. Therefore the outbreak rate of Cutaneous Leishmaniasis has expressed an extensive growing in north east, south east and central regions of Iran [5]. Most famous communities where considerable rate of Cutaneous Leishmaniasis outbreak has been reported in Iran are the following regions: Mashhad, Neyshabur, Shiraz, Kerman, Qom, Saveh, Isfahan, Kashan and Sabzevar [6]. World health organization (WHO) has categorized this disease among 10 high risky diseases and considered it in the group of uncontrolled, returnable and expandable diseases. Regarding the last update, the numbers of patients with Leishmaniasis who have been reported by now are almost 20000 patients [7]. This disease after Malaria has been recognized as the most important parasitic disease in Iran, Compounds including Antimovan with 5 electron holes, such as glucantime and pentosan have been discovered as the first line in the treatment of this disease [8]. The causes for choosing of the treatment of patients with intramuscular injection is the short duration of treatment compared to other methods and the number as well as type of recorded patient's lesion according to the national protocol, and limited performed studies on this type of treatment compared to further treatment methods including Cryotherapy and injection. Therefore, consideration of high prevalence of this disease in the whole world and in Iran as well as in Sabzevar (city where this research has been performed), and its importance due to the complications in some of the studied patients, have encouraged the authors of the current study to research on the causes of treatment discontinuation in patients with Cutaneous leishmaniasis with the use of muscle injection of glucantime with respect to the type of the applied medicines' side effects.

Methods

The present study is a cross-sectional descriptive-analytic study performed on all patients who were candidates for the

systemic glucantime treatment in Sabzevar city in 2016 according to the country national protocol. Regarding that protocol, systemic treatment is completed in the following cases:

1. Lesion on the face
2. The number of 5 or more
3. Diameter greater than 3 cm
4. Esporotricose
5. Lesion on the joint
6. Recurrence or treatment failure

The total number of samples was set on 54 (including 31 males and 23 females). In the present study, the relationship between demographic factors (including age, sex, history of disease, weight, location of the lesion), systemic symptoms (including gastrointestinal and general effects), alterations in pancreatic enzyme levels, Liver enzyme levels, CBC, BUN, and CR with incidence of complications during systemic glucantime injections of 3 weeks were studied. Before the treatment, all of CBC, BUN, Cr, liver and pancreatic enzymes of the studied patients were tested, all of the taken samples were detected normal. For patients with the age rather than 60 years, ECG and cardiac examinations were performed based on the weight of the patients. According to the National Protocol, for each 20 kg of body weight per day, 1 injection was done (max. 3 injections through 20 days). At the end of the first and second weeks of the treatment, the above mentioned experiments were requested and applied for each patient, in the case of alterations in the obtained results, including 3-fold increases in liver enzymes and pancreatic enzymes' level as well as 30% reductions in the hematocrit and hemoglobin levels, the treatment process was stopped for the studied patients.

Findings

The present study was performed on 54 patients (31 males (57.4%) and 23 females (42.6%)) who had been treated by glucantime muscle injection in Sabzevar city-Iran at 2016.

The highest number of patients was 22 (40.7%) with the age ranged ≤ 60 and most of the 27 patients had shown no history of heart disease, diabetes, etc. Among the patients who were diagnosed with complications and the discontinuation of treatment was done on them, 50% (27 patients) showed systemic symptoms that the incidence of complications and discontinuation in treatment with the onset of systemic symptoms was statistically detected significant (p -value <0.0001). Among 54 selected patients, 25.9% (14 patients) at the end of the first week, 18.5% (10 patients) at the end of the second week and only 5.6% (3 patients) at the end of the third week have shown systemic symptoms, moreover 38.9% (21 patients) showed pancreatic enzymes enhancement of which in 14.8% (8 patients) enzyme levels got enhanced 3 folds, finally treatment process was stopped for those 8 patients, statistically between the incidence of complications and pancreatic enzyme alterations significant differences were detected (p -value <0.006). Among 54 patients, 7.4% (4 patients) and 7.4% (4 patients) at the end of the first and second weeks respectively, showed the symptoms (enzymes level increased 3 folds), finally this phenomenon led to discontinuation of treatment of the patients. According to the findings, among the studied patients, 1.9% (1 patient) showed liver enzymes enhancement, 9.3% (5 patients) expressed CBC alterations and 5.6% (3 patients) indicated BUN, regarding the alterations protocols, these alterations were not

in a range to be applied for discontinuation of treatments process. The most cases of lesion (alone or joint with the rest) were detected in the hands of the studied patients (23 patients and-or 42.6%), forearms (21-38.9%), feet (18.33%) and legs (17-31.5%). There was no statistically significant correlation between the location of the lesion and the incidence of the disease (p -value <0.460).

Based on the obtained results, it was detected that, the highest incidence of complications based on the patients' weight was 13 patients (24.4%) at the end of the first week that was not statistically significant (p -value <0.089), where among 13 patients, 11 ones were in the age ranged 60, 2 left ones were in the weight ranged 20-40 kg, generally patients with the weight over ≤ 60 showed the highest complication during treatment period. The highest complication related to gender was detected at the end of the first week on about 13 patients (24.1%), which the incidence of complication in males through treatment period is higher compared to females, but it was not statistically significant (p -value <0.086).

The highest complication rate related to age was at the end of the first week (13 patients) that was statistically significant (p -value <0.023). Most of the patients in this week 40.7% (22 patients) were in age over than 60 years, but regarding the findings, the highest incidence of complication in the total period of treatment in patients in age ranged 50-59 years was determined equals to 83.3%.

Discussions and Conclusion

Sabzevar city is one of the target cities that Cutaneous leishmaniasis has shown considerable outbreak. Since, the first step in the treatment of this disease is Glucantime application (injection) [5], thus the aim of the current research is to study the causes of treatment discontinuation in patients with Cutaneous leishmaniasis who are under muscle glucantime injection treatment based on medicine complications. The achieved results presented that, Cutaneous leishmaniasis in males is a more common disease compared to women in Iran, it may be due to their coverage and activities in open environments leading to a decrease in Cutaneous leishmaniasis report, this result is in solid agreement with those achieved by Saghafipour et al. [4,7].

According to the obtained results, the patients with Cutaneous leishmaniasis in age less than 60 years, are the highest and the occurrence of medicine complications was the highest in age ranged 50-59 years, the cause of medicine adverse effects may be due to reductions in immune system of patients, while in further studies the highest number of patients with the complications was less than 10 patients [1,4]. The cause of this difference may be due to the location of patients in the city where most of the patients in the current age were farmers living in suburb of the above mentioned city, therefore due to the environmental pollutions, they have been exposed under the effects of Mosquitoes transmitting Cutaneous leishmaniasis. In the present research 27 patients (50%) were successful to pass the treatment while in the achieved results of mohammadzadeh et al, refractive index was reported 22.6%, the causes of differences in the achieved results of different studies may be due to a break in treatment with glucantime injection in bodies with the weights over 68 kg, number of skin lesions ≤ 3 and failure to complete the treatment program [5], where in the present study, the most highest numbers of people with Cutaneous leishmaniasis were in age over than 60 years and weight rather than 60 kg, in that condition the break rate showed enhancements.

In the current research the highest complication was discovered in hands of the selected patients, this result was in solid agreement with the achieved results of Hazavi (hands with 47%) and Mokhtari (31.5%) [9, 10] and was in disagreement with the achieved results of Taghvaiee and Sofizadeh that in the two last studies the highest complication was discovered in faces of the selected patients [4,9-11]. Regarding the fact that, summer is a peak time of regeneration and nourishing of Mosquitoes [12] and the current study has been performed in such a hot and dry climate, therefore the coverage and job titles of the patients should be effective in the incidence of complication rate. The performed studies demonstrated that most of the patients may tolerate the treatment time of Cutaneous leishmaniasis but some of them showed pancreatic complication as a common complication [13]. In the current study enhancements in pancreatic enzyme levels with incidence time of complication expressed significant differences. According to the performed studies, after pancreatic complication, treatment process must be stopped and further treatment methods should be used [14]. In the present study, immediately after pancreatic enzymes alteration up to 3 folds (regarding the report of the Internist), treatment process was stopped and Cryoterhapy was used instead. Further discovered complications of this phenomenon may refer as nausea, vomiting, disorders in the levels of liver enzymes, pain at the injection site once the medication is muscle and alterations in ST-T waves, moreover in term of not observation of standard dose (20 mg. Kg⁻¹) heart complication and finally sudden death may happen [13]. In the present research systemic complications including general and gastrointestinal complications was discovered in more than half of the patients leading to a discontinuation of treatment, these symptoms in treatments with the use of muscle injection unlike local injection method with glucantime that is sustainable, have been categorized in the cases of discontinuation of treatment [1].

According to the obtained findings, it may be concluded that, the causes of discontinuation in treatment in the current research might be incidence of systemic complication and enhancements of pancreatic enzymes due to glucantime muscle injection, occurred mostly in the first weeks of treatment period and finally leading to the application of alternative methods such as cryotherapy for patients.

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