

Clinical audit: Baseline investigations for intramuscular meglumine antimoniate in cases of cutaneous leishmaniasis

Mansoor Dilnawaz, Zafar Iqbal Shaikh, Hina Mazhar, Imran Shafi, Majid Hussain

Department of Dermatology, Military Hospital, Rawalpindi

Abstract *Objectives* To see if the baseline investigations for intramuscular meglumine antimoniate in cases of cutaneous leishmaniasis were being carried out in accordance to our local guidelines.

Patients and methods 30 case records of patients with cutaneous leishmaniasis were randomly selected from our dermatology ward. These records were reviewed to see if the pre-therapy investigations for meglumine antimoniate were carried out. The method of data collection was retrospective.

Results The result showed 100% compliance with our local guidelines in the analyzed cases.

Conclusion Our audit showed 100% compliance.

Key words

Clinical audit, meglumine antimoniate, cutaneous leishmaniasis

Introduction

Leishmaniasis is one of the major health problems in the world.¹ Pakistan has a considerable number of leishmaniasis cases, both cutaneous and visceral. Prevalence has been estimated at 2.7% in the northwestern part of the country with incidence at 4.6 cases/1000 persons/year over the last ten years.²

Many therapeutic modalities are suggested; there is no definite treatment for this condition. Antimony compounds such as sodium stibogluconate (pentostam™) and meglumine antimoniate (glucantime™) are regarded as the first-line treatment for leishmaniasis.³ Though considered generally safe medications⁴, many

serious cardiovascular, hematological, renal and hepatic complications have been found to be associated with their use.⁵ It is therefore important to perform pre-therapy and monitoring investigations in order to keep an eye on their potential side effects. This retrospective clinical audit was designed to see whether baseline investigations were being performed or not as per our local guidelines.

Patients and Methods

30 case-records of patients with cutaneous leishmaniasis were randomly selected from our dermatology ward. These records were reviewed to see if the pre-therapy investigations for meglumine antimoniate were carried out. The method of data collection was retrospective. The basis of proposal was our local guidelines. The audit type was process. The samples sources were case-notes of histologically diagnosed patients of cutaneous leishmaniasis admitted in our dermatology ward. The sample size was 30 case records. A

Address for correspondence

Dr. Mansoor Dilnawaz
Consultant Dermatologist
Department of Dermatology
Military Hospital (MH), Rawalpindi
Email: mdilnawaz@gmail.com
Tel: 0342-4210568

data collection pro forma was used. The collected data was analyzed according to the pre-set criteria and standards. The criteria were “all the diagnosed cases of cutaneous leishmaniasis requiring treatment with intramuscular meglumine antimoniate should have the baseline tests comprising complete blood counts, liver function tests, renal function tests and electrocardiogram”. The standard was “100% patients requiring intramuscular meglumine antimoniate should have all the above named investigations done before going ahead with this treatment modality”.

Results

The analysis of all the 30 case-notes showed that 100% patients had all these baseline tests done before starting on intramuscular meglumine antimoniate. This was in accordance to our local guidelines. The sociodemographic data and the clinical characteristics (**Table 1**) showed mean age of patients 29.57 years, mean duration of illness 3 months, 27 (90%) males, 3 (10%) females, unmarried 12 (40%), married 18 (60%), single skin lesion 18 (60%), multiple skin lesions 12 (40%), lesions on the arms 10 (33%), hands 9 (30%), face 7 (23%), legs 4 (13%). None of the patients had any prior medication before starting on intramuscular meglumine antimoniate. 100% patients (n=30) had all the baseline blood tests done according to our local guidelines. The recommendations were to continue with good practice of advising these baseline investigations to preempt the potential side effects of these antimonials. A *re-audit* is planned in 6-month time to see if this good practice is maintained.

Discussion

Cutaneous leishmaniasis (CL) is an important health problem in endemic areas⁶ and is found

Table 1 Sociodemographic data and clinical characteristics (n=30).

Variables	Results
Mean age (years)	29.57 years
Gender	
Male	27 (90%)
Female	3 (10%)
Marital status	
Married	18 (60%)
Unmarried	12 (40%)
Mean duration of disease duration	3 months
Number of skin lesions	
Single	18 (60%)
Multiple	12 (40%)
Distribution of lesions	
Arms	10 (33%)
Hands	9 (30%)
Face	7 (23%)
Legs	4 (13%)
Prior medication	0 (0%)

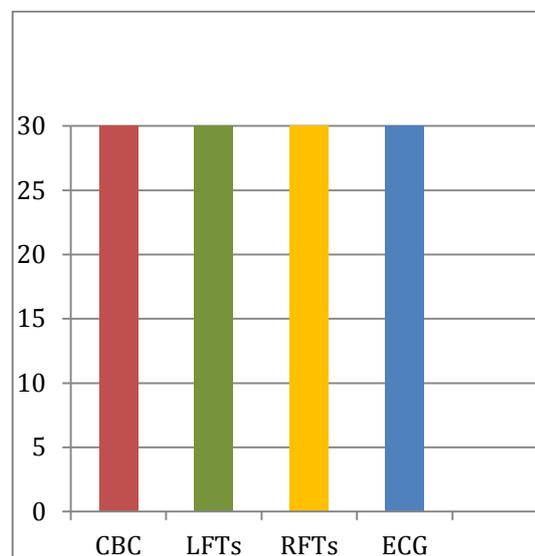


Figure 1 Result of baseline tests for intramuscular meglumine antimoniate. CBC=complete blood count, ECG=electrocardiography, LFTs=liver function tests, RFTs=renal function tests.

in more than 80 countries. The World Health Organization reports an annual incidence of 1.5 million cases per year. An estimated 12 million people are infected from a population of 350 million people who are at risk.⁷ Outbreaks of CL have largely been reported from northern areas of Pakistan especially with the arrival of Afghan refugees.^{8,9} Mostly the reason has been the settlement of a large population in the natural habitat of sandfly.¹⁰

Although CL is a self-healing disease, it can result in disfiguring scar and long-lasting stigmas with destruction of underlying structures that may cause significant morbidity and may also affect psychological health of patients. Several therapies are proposed for treatment of CL.¹¹ The pentavalent antimonials sodium stibogluconate (pentostam™) and meglumine antimoniate (glucantime™) have maximum efficacy.¹² The mechanism of action of these agents is suppression of the phosphofructokinase activity resulting in blocked ATP production.⁴

It is estimated that more than 200,000 patients have been treated with pentavalent antimony compounds in the past 80 years.¹³ There are just two reports of death following drug administration. It is not clear whether this was because of the drug side effects or the disease process itself.¹⁴ This means that these are relatively safe agents. The most frequently seen adverse effects include nausea, vomiting, abdominal pain, diarrhea, cough, pneumonia, bleeding tendency, skin reactions (e.g. erythema and urticaria), albuminuria, convulsion, bradycardia, ECG changes such as prolonged QT interval and flat T wave,¹⁵ myositis, muscle pain,^{14,16} pancreatitis,¹⁷ derangement of renal functions.^{18,19} It was noted that the most side effects were reported in patients treated with high doses of meglumine antimoniate (20mg/kg/day of antimony salt). In order to monitor such side effects it is mandatory to know the baseline clinical and biochemical status of the patient by performing baseline tests like complete blood counts, liver function tests, renal function tests and electrocardiogram. Our local guidelines included these baseline tests and our audit showed 100% compliance.

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