

# Clinical audit on treatment of mucosal and multiple cutaneous leishmaniasis lesions with pentavalent systemic antimony

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**Abstract** *Background* Cutaneous leishmaniasis is a parasitic disease spread by the female sandfly occurring throughout the Americas from Texas to Argentina, and in the Old World, particularly the Middle East and North Africa. The condition is diagnosed every year in travelers, immigrants, and military personnel. The treatment mainstay is pentavalent antimony (e.g., sodium stibogluconate). Not all patients require treatment; many lesions heal spontaneously. The treatment is usually indicated in mucosal, mucocutaneous and multiple active cutaneous lesions.

*Methods* 30 patients of cutaneous leishmaniasis were included from the dermatology ward. The method of data collection was retrospective. The basis of proposal was local guidelines. The audit type was process. The standard set was “100% patients with mucosal and multiple cutaneous leishmaniasis lesions should be treated with pentavalent systemic antimonials”.

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

**Key words**

Clinical audit, cutaneous leishmaniasis.

## Introduction

Leishmaniasis is a major cause of illness and death and a top priority for the tropical disease program of WHO. Globally, there are an estimated 1.5-2 million new cases and 70,000 deaths each year, and 350 million people are at risk of infection and disease.<sup>1</sup> In Pakistan the prevalence has been estimated at 2.7% in the North-Western part of the country with incidence at 4.6 cases/1000 persons/year over the last ten years.<sup>2</sup> Pentavalent antimony compounds like meglumine antimoniate are the main therapeutic agents for various forms of leishmaniasis.<sup>1</sup> In view of the usual need for parenteral administration, side effects profile and emergence of resistant strains, there has

been an intensive search for alternative therapies for cutaneous leishmaniasis like certain azole antifungal drugs which have activity against leishmania.<sup>3,4</sup>

## Methods

30 patients with mucosal and multiple lesions of cutaneous leishmaniasis were included from the dermatology ward. The method of data collection was ‘Retrospective’. The basis of proposal was ‘Local Guidelines’. The audit type was ‘Process’. The sample source was ‘Case-Notes’ from the dermatology ward. The sample size was 30 cases. A data collection proforma was used. The collected data was analyzed according to the pre-set criteria and standards. The criteria were “All patients with mucosal and multiple cutaneous leishmaniasis lesions should be treated with systemic antimonials”.

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

<i>Variable</i>	<i>Result</i>
Mean age	31 years
Gender	
Male	30 (100%)
Female	0
Marital status	
Married	17 (56.6%)
Unmarried	13 (43.4%)
Lesional status	
Mucosal	6 (20%)
Scattered	19 (63.3%)
Grouped	5 (16.6%)

The standard was “100% patients with mucosal and multiple cutaneous leishmaniasis lesions should be treated with systemic antimonials”. The inclusion criteria included age 12 or more, both gender, active mucosal or skin lesions, no known allergies, side effects or co-morbidities especially related to systemic antimonials. The exclusion criteria included age less than 12, pregnancy and breastfeeding, known allergies or side effects to systemic antimonials and already substantially regressed lesions.

## Results

The analysis of all the 30 records showed that 100% patients with mucosal and multiple cutaneous leishmaniasis lesions were treated with systemic antimonials. There was no contraindication or side effects in any of the treated patients.

This was in accordance with our local guidelines. The sociodemographic data and the clinical characteristics (**Table 1**) showed mean age of patients 31 years, males 100% (n=30), females 0% (n=0), married 56.6% (n=17), unmarried 43.4% (n=13), mucosal lesions 20% (n=6), scattered lesions 63.3% (n=19), grouped lesions 16.6 % (n=5) (Fig 3). The common sites involved included upper and lower limbs, lips, nose and ear. The recommendation was to continue with this good clinical practice. A re-audit is planned in 6-month time to see if this good practice is maintained.

The audit is summarized in **Table 2**.

**Table 2** Audit summary.

<i>Rationale</i>	Evidence-based and correct treatment of mucosal and multiple cutaneous leishmaniasis lesions like any other medical condition is important.
<i>Objective(s)</i>	The aim of this audit was to see if the active mucosal and multiple cutaneous leishmaniasis lesions were being treated in accordance with our local guidelines
<i>Project type</i> <i>Basis of proposal</i>	Process Local guidelines
<i>Criteria</i>	The patients with active mucosal and multiple cutaneous leishmaniasis lesions should preferably be treated with systemic antimony
<i>Standard(s)</i>	100% patients with mucosal and multiple cutaneous leishmaniasis lesions should be treated with systemic antimony
<i>Sample source</i>	Case-records of patients admitted in the dermatology ward
<i>Sample size</i> <i>Data collection/ analysis</i>	30 case-notes Retrospective
<i>Results</i>	The result showed 100% compliance with our local guidelines
<i>Recommendations/ Areas for improvement</i>	The recommendation was to continue with this same good clinical practice of treatment of leishmaniasis patients
<i>Re-audit</i>	6-months

## Discussion

Many cutaneous leishmaniasis (CL) infections eventually resolve clinically without treatment, and not all patients who undergo treatment demonstrate elimination of parasitic infection.<sup>5</sup> The benefits of treatment include accelerated healing of skin lesions<sup>6,7</sup> reduced likelihood of recurrence (especially in the setting of subsequent immune compromise), diminished severity of skin scarring and attendant emotional concerns.<sup>8,9</sup> The aim of CL treatment is clinical cure, not parasitologic cure. Treatment decisions must include consideration of individual risks and benefits, which can be complex given the large number of parasite species with variable clinical syndromes, complications, and rates of spontaneous resolution.

CL is a parasitic disease occurring throughout the Americas from Texas to Argentina, and in the Old World, particularly the Middle East and North Africa. It is spread by the female sandfly. The condition is diagnosed every year in travelers, immigrants, and military personnel. Physicians working for short periods in endemic areas often must make the diagnosis and should be aware of local disease patterns. When faced with a possible leishmanial skin lesion, a skin scraping with microscopic analysis is the best test. Punch biopsies with tissue-impression smears also can be diagnostic. Needle aspiration of tissue fluid from the margin of a lesion can yield fluid for culture to isolate the organism and identify the species. Immunologic tests are being developed, including a highly sensitive polymerase chain reaction test. The treatment mainstay is pentavalent antimony (e.g. sodium stibogluconate). Not all patients require treatment; many lesions heal spontaneously. Antimonials have a high incidence of reversible adverse effects.<sup>10</sup> In a military study,<sup>11</sup> 96 subjects with leishmaniasis (83 cases were cutaneous) were treated for 20 to 28 days and followed for one year. Side effects

included body aches, arthralgia, fatigue, gastrointestinal upset, and elevation of amylase, lipase, and liver enzyme levels, leukopenia, anemia, and electrocardiographic abnormalities. Other medications used for treatment include amphotericin B, pentamidine, paromomycin, and antifungals. This disease must be considered in at-risk patients, and physicians should know the basics of diagnosis and where to go for more help.

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